

Serim®

GUARDIAN™

HiSENSE™

Test for low levels of
total chlorine
(chloramines/free chlorine)
in treated water

DESCRIPTION

The SERIM® GUARDIAN™ HiSENSE™ Test Kit (Product Code 5109) provides a convenient means for indicating **low levels** of total chlorine (chloramine and/or free chlorine) in water used to prepare dialysate.

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

A negative result with a test sensitive to 0.1 mg/l total chlorine, will indicate that the concentration of total chlorine in the treated water is less than the maximum allowable concentration of 0.1 ppm for chloramine.¹ The chloramine concentration will always be less than or equal to the total chlorine concentration.

A positive result from a SERIM HiSENSE Test Strip indicates that the water should not be used to prepare dialysate and that the carbon adsorption media in the water purification system may need to be replaced.

The SERIM GUARDIAN HiSENSE Test Kit contains ready-to-use Test Strips, Strip Holder and Reagent Solution necessary for detection of total chlorine.

The Association for 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

SERIM offers a HiSENSE Accessory Pack (Product Code 5109AP) containing supplementary components sufficient to make five individual test kits when used in combination with kit #5109.

CHEMICAL PRINCIPLES OF THE TEST

The HiSENSE Test Strip Paper Flap contains a colorless indicator and the HiSENSE Reagent Solution contains potassium iodide in a phosphate buffer.

Free chlorine and/or monochloramine in the water sample oxidizes the iodide from the HiSENSE Reagent Solution to iodine. As the sample drains through the Paper Flap of the HiSENSE Test Strip, the iodine oxidizes the colorless indicator to a colored product.

Step 1:



Step 2:



WARNINGS AND PRECAUTIONS

- Use HiSENSE to test **treated water prior to** preparing dialysate.
- Do not touch the reagent-containing Paper Flap on the HiSENSE Test Strip.
- Do not allow the HiSENSE Test Strip to come in contact with liquids or with work surfaces which may be contaminated with interfering substances.
- Do not use HiSENSE test materials in areas where vapors from containers of bleach or other oxidizing solutions may be present.
- Do not use a test strip (from an opened or unopened bottle) after the expiration date.
- Do not use HiSENSE Reagent Solution after the expiration date.
- Keep all unused strips in the original bottle.
- Do not remove the desiccant pack.
- Replace cap immediately and tightly after removing a strip; the strips must be protected from humidity and heat.
- This is a **single use device**. After use discard the test strip according to federal, state and local regulations.

STORAGE

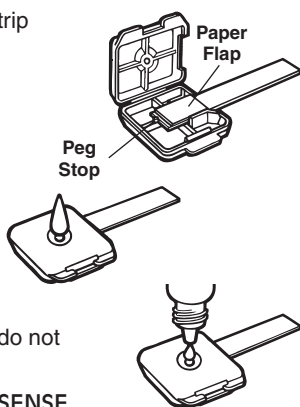
- The SERIM GUARDIAN HiSENSE Test Strips must be kept in the original bottle with the lid tightly closed.
- Do not remove the desiccant pack.
- Store at temperatures between 15°–30°C (59°–86°F).
- **Use within 3 months after first opening the bottle.**
- Always write the date opened in the space provided on the bottle label.
- Do not store the test materials in areas where vapors from containers of bleach or other oxidizing solutions may be present.
- Lot number and expiration date are printed on the bottom of the bottle.

DIRECTIONS

Testing for presence of low levels of monochloramine and/or free chlorine:

Note: Since low levels of chlorine and chloramine are not stable during prolonged storage (particularly in the presence of light), begin the test procedure immediately after collecting the sample.

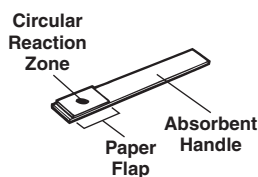
1. Remove one HiSENSE Test Strip from bottle. Replace the cap promptly and tightly.
2. Insert the HiSENSE Test Strip into the Strip Holder (with the Paper Flap facing up) until it meets the peg stop. Snap the Strip Holder closed.
3. Add the water sample drop-wise until the reservoir in the Strip Holder is just full (do not overfill).
4. Immediately add **1 drop** of HiSENSE Reagent Solution to the sample in the reservoir. (Addition of more than 2 drops of HiSENSE Reagent Solution will adversely affect the sensitivity of the test.)
5. When the sample has drained (approximately 8 minutes), remove the HiSENSE Test Strip from the holder and interpret according to the information given in the following RESULTS section.



RESULTS

Note: The results from a HiSENSE Test Strip must be interpreted within 10 minutes after the sample has drained.

Positive – If the circular Reaction Zone (the circular area under the reservoir opening) of the HiSENSE Test Strip displays a blue color that is darker than the surrounding area of the Paper Flap, the water tested should not be used to prepare dialysate.



Note: The higher the monochloramine/free chlorine concentration in the sample, the more intense the blue color in the Reaction Zone.

Negative – If the circular Reaction Zone of the HiSENSE Test Strip is no darker than the rest of the Paper Flap, the water tested has levels of less than 0.1 ppm total chlorine.

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 (Product Code 5109).

PERFORMANCE CHARACTERISTICS

In actual samples found in the field, significant levels of either free chlorine or chloramine will not exist in the presence of the other; thus one of the forms will predominate. Furthermore, the predominant form of chloramine is in the form of monochloramine. Therefore, the performance characteristics of SERIM GUARDIAN HiSENSE Test Kit are based on analytical studies using water samples to which either monochloramine or sodium hypochlorite was added to give a range of monochloramine or free chlorine concentrations, respectively. Amperometric titration was used as the reference method⁵ for measuring the monochloramine or free chlorine concentrations in the samples.

Total chlorine concentrations of 0.1 ppm or greater in water samples of widely varying properties will consistently produce a positive result. The sensitivity of the test strip depends on several factors including variation in an individual's color perception, the variation in lighting conditions and the possible presence of interfering substances.

Test Strip results on samples containing 0.05 ppm monochloramine were not hampered by the presence of the following common water constituents up to the indicated concentrations:

Hardness (1000 ppm as calcium carbonate);
 Total alkalinity (500 ppm as calcium carbonate);
 Ferric ion (1.1 ppm); Ferrous ion (1.0 ppm);
 Cupric ion (2.0 ppm); Nitrate (50 ppm as nitrogen);
 Nitrite (5 ppm as nitrogen); Sodium chloride (1100 ppm sodium ion and 1700 ppm chloride); Sulfate (1100 ppm);
 pH range of 7.3 to 10.1; and a pH of 10.1 with an alkalinity of 510 ppm.

None of the above substances interfered with the detection of samples containing 0.1 ppm free chlorine except nitrite and ferrous ions which destroy free chlorine by reduction.

SENSITIVITY

In blind studies, either distilled water or contrived tap water containing 0.025-ppm monochloramine tested positive in all cases. When contrived tap water is adjusted to pH 10 and 500 ppm alkalinity, 0.025 ppm and 0.05 ppm monochloramine tested positive in 13 and 100 percent of the determinations, respectively.

LIMITATIONS

SERIM GUARDIAN HiSENSE Test Strips will give qualitative, positive results with any substance that will oxidize iodide to iodine. These substances, which should not be present in carbon-treated water, include among others chlorine dioxide, ozone, bromine, peroxides and peracetic acid. The reaction of these substances with the HiSENSE Test is potentially advantageous, as the operator should be alerted to any oxidizing substances that appear in the carbon-treated water.

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 *Standard Methods for the Examination of Water and Wastewater*, 19th Edition (American Public Health Association, Washington, D.C., 1995).

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