



## HISENSE ULTRA 0.1™

Test for Total Chlorine  
in feed or rinse water

### DESCRIPTION

SERIM® HISENSE ULTRA 0.1™ Test Strips (Product Code 5167) provide a quick and convenient means for indicating low levels of total chlorine (chloramine/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) detected in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.

Using a 30-second semi-quantitative procedure, the strips will detect total chlorine levels 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; 0.1 ppm is the AAMI (Association for the Advancement of Medical Instrumentation) maximum allowable concentration of chloramine in feed water.<sup>1</sup>

In feed water, a result of 0.1 ppm chloramines or above indicates that the water should not be used to prepare dialysate because of chloramine breakthrough or exhaustion of the carbon adsorption media in the water purification system. NANT (National Association of Nephrology Technicians/Technologists) recommends that feed water samples should be obtained after the first carbon tank to monitor chlorine/chloramine levels.<sup>2</sup>

For rinse water following disinfection of hemodialysis equipment, a result of 0.5 ppm free chlorine or above indicates that further rinsing is needed.<sup>1</sup>

### CHEMICAL PRINCIPLES OF THE TEST

SERIM 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.<sup>3 4 5</sup>

Reduced Indicator  
+ Free Chlorine



Oxidized Indicator +  
 $H_2O + HCl$   
(pink/purple)

Monochloramines  
+ Reduced Indicator



Oxidized Indicator  
(blue/purple)

### WARNINGS AND PRECAUTIONS

- Do not use SERIM HISENSE ULTRA 0.1 Test Strips to determine chlorine potency.
- Keep all unused test strips in the original bottle.
- Do not remove desiccant pack.
- Replace cap immediately and tightly after removing a strip.
- Do not use the SERIM HISENSE ULTRA 0.1 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.

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

### STORAGE

- All SERIM 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).
- 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 bottom of the bottle.

### DIRECTIONS

#### Qualitative Rinse Water Procedure for Residual Chlorine Testing

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.

#### Results:

- PASS-** If no color is immediately apparent, the residual chlorine level 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 Feed or Rinse Water Total Chlorine Testing (chloramines or free chlorine)

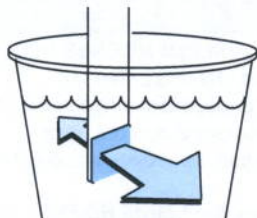
An estimate of the concentration of chlorine in water is obtained by comparing the color of the indicator pad with the color blocks on the bottle label.

1. Using the sample cup provided, fill with ~20 ml of water. Discard contents and re-fill before testing.



2. Immerse indicator pad in sample solution and swish test strip back and forth vigorously for 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 to remove excess sample. Compare color of the indicator pad to the color chart immediately.

Color blocks are designated at 0 ppm, 0.1 ppm, 0.5 ppm, and 3.0 ppm (0 mg/L, 0.1 mg/L, 0.5 mg/L, and 3.0 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.

### 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.

### PERFORMANCE CHARACTERISTICS

The performance characteristics of the **SERIM 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.<sup>6</sup>

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.

**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.

### LIMITATIONS

**SERIM 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, monochloramine, nitrogen trichloride, iodine, and bromine. **SERIM HISENSE ULTRA 0.1** Test Strips are not suitable for testing chlorine in bicarbonate concentrates or dialysate.

### REFERENCES

- <sup>1</sup> Association for the Advancement of Medical Instrumentation, 2005 Dialysis Edition (ANSI/AAMI RD62: 2001) Section 4.2.2, Table 1; published by the Association for the Advancement of Medical Instrumentation, Arlington, Virginia.
- <sup>2</sup> Dialysis Technology — A manual for dialysis technicians, Second Edition, page 109. National Association of Nephrology Technicians/Technologists (NANT), Dayton, OH, 2000.
- <sup>3</sup> 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.
- <sup>4</sup> R. Bauer, B.F. Phillips and C.O. Rupe, "A Simple Test for Estimating Free Chlorine," Journal AWWA (November 1972), pp. 787-789.
- <sup>5</sup> 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.
- <sup>6</sup> "Amperometric Titration Method," Standard Methods for the Examination of Water and Wastewater, 19<sup>th</sup> Edition (American Public Health Association, Washington D.C., 1995), pp. 4-41 to 4-43.

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