Serim®

GUARDIAN™

RESIDUAL CHLORINE

Test for residual chlorine in rinse solution

DESCRIPTION

Serim® GUARDIAN™ RESIDUAL CHLORINE Test Strips (Product Code 5100A and 5100C) provide a convenient means for indicating the concentration of chlorine bleach (sodium hypochlorite) remaining in the solution used to rinse dialysate lines following disinfection of hemodialysis equipment.

Chlorine bleach detected in the rinse solution is normally referred to as "residual chlorine." The results of the test indicate the level of chlorine bleach remaining in the dialysate lines at any point during the rinsing process.

Using a rapid screening method, the strips will detect chlorine levels at or above 0.5 ppm while a 30-second semi-quantitative method allows estimation of concentrations between 0 and 5 ppm.

The qualitative rapid screening method can be used to determine that chlorine has been adequately rinsed from the machine. The semiquantitative method may be useful where corrective measures are undertaken on machines dispensing unacceptable levels of chlorine for extended periods and for testing containers, i.e., "bicarb jugs," disinfected with bleach.

The **Serim GUARDIAN RESIDUAL CHLORINE** Test Strips are supplied in a ready to use form. When placed in contact with the rinse solution according to directions, the indicator pad changes color relative to the amount of chlorine remaining in the rinse solution. Results of 0.5 ppm or above indicate that further rinsing is necessary.[1]

CHEMICAL PRINCIPLES OF THE TEST

Serim GUARDIAN RESIDUAL CHLORINE Test Strips react with total chlorine, i.e., free chlorine and monochloramine. The indicator pad on the test strip is buffered to a pH of 6.8 and contains an indicator and potassium iodide. Free chlorine oxidizes the colorless indicator compound to form pink/purple oxidation products. Monochloramine oxidizes the potassium iodide to iodine, which in turn oxidizes the indicator to the colored form.[2, 3, 4]

$$\text{Reduced Indicator} + HOCl \longrightarrow \underset{\text{(pink/purple)}}{\text{Oxidized Indicator}} + H_2O + HCl$$

$$\text{Monochloramine} + I^- \longrightarrow I_2 + NH_3 + Cl^-$$

$$\text{Reduced Indicator} + I_2 \longrightarrow \underset{\text{(pink/purple)}}{\text{Oxidized Indicator}}$$

WARNINGS AND PRECAUTIONS

- Do not use **Serim GUARDIAN RESIDUAL CHLORINE** Test Strips to determine chlorine potency. High concentrations of chlorine will inhibit the reaction and yield an invalid result.
- Do not use **Serim GUARDIAN RESIDUAL CHLORINE** Test Strips to measure low levels of chloramine in treated water. These strips are not sensitive enough to meet the AAMI standard of 0.1 ppm chloramine for treated water used in making dialysate. To test for *low levels* (0.1 ppm) of chloramine and free chlorine in treated water, request: Product Code 5109 Serim® HiSENSE Test Kit or Product Code 5167 HiSENSE ULTRA 0.1™ Test Strips.
- Keep all unused test strips in the original bottle.
- Do not remove desiccant pack.
- Replace cap immediately and tightly after removing a strip; the strips must be protected from humidity.
- Do not touch the indicator pad.
- Do not allow the pad to come in contact with liquids or with work surfaces that may be contaminated with potentially interfering substances.
- Do not leave strips outside the bottle in areas exposed to chlorine vapors or other oxidizing vapors.
- Do not leave the bottle or individual strips laying on the dialysis machine as the heat from the machine will degrade the reactivity of the strips.

STORAGE

- **Serim GUARDIAN RESIDUAL CHLORINE** 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.
- Expiration date and lot number are printed on the bottom of the bottle.

DIRECTIONS

Qualitative Method:

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 color.

Results:

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

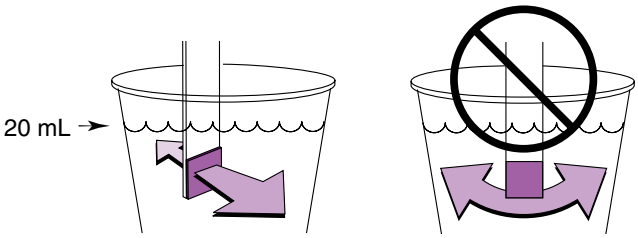
FAIL- Any pink or purple color indicates that a residual chlorine concentration of 0.5 ppm or greater is present and additional rinsing is required.

Note:

- When using the qualitative method, **do not** refer to the color blocks on the bottle label to determine the concentration of residual chlorine.
- To obtain accurate results with the qualitative method, a stream of rinse solution is required. Invalid results will be obtained if the indicator pad is dipped into a sample of the rinse solution or held in rinse stream for periods greater or less than 5 seconds.

Semi-Quantitative Method:

1. Using a clean container, fill the container with sample. Discard contents and re-fill (~20 mL of sample required).



Pad perpendicular to direction of movement. (Fig. 1)

Do not move strip with pad parallel to direction of movement. (Fig. 2)

2. Immerse indicator pad of test strip in sample solution and **move strip back and forth vigorously for 30 seconds.** The indicator pad must be perpendicular to the direction of strip movement (Fig. 1).
3. Remove strip and compare to color chart within 10 seconds.

Results:

An estimate of the concentration of chlorine in rinse solution is obtained by comparing the color of the indicator pad with the color blocks on the bottle label. The color blocks are calibrated in terms of chlorine concentration in parts per million (ppm). Color blocks are designated as 0 ppm, 0.5 ppm (0.5 mg/L), 1 ppm (1 mg/L), 2 ppm (2 mg/L) and 5 ppm (5 mg/L) 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 (particularly in the presence of light), 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 the inadvertent use of outdated product or product that has deteriorated due to improper storage or handling.

Serim supplies Chlorine Control Tablets (Product Code 5100QC) for use in preparing an operational Positive Control Solution. The Control Solution is a substitute for chlorine. The final color reaction on the strip will mimic the presence of chlorine; i.e., it will simulate a positive result. However, the Control Solution does not actually contain chlorine.

Preparation of a Positive Control Solution:

1. Fill the sample cup to the 20 mL line with chlorine-free water.
2. Drop in one Chlorine Control Tablet and wait 2 minutes.

Preparation of a Negative Control Solution:

1. Collect 20 mLs of chlorine-free, AAMI-quality water for use as a Negative Control Solution.

Test Procedure for Control Solutions:

1. Immerse indicator pad of test strip in sample solution and **move strip back and forth vigorously for 30 seconds.** The indicator pad must be perpendicular to the direction of strip movement (Fig. 1).
2. Remove strip and compare to color chart within 10 seconds.

If results with the Quality Control Solutions are not as expected, do not use that particular bottle of Serim GUARDIAN RESIDUAL CHLORINE Test Strips. Retain the bottle and any remaining strips and call Serim at 1-800-542-4670 or (574) 264-3440 or your local Serim dealer. Open a new bottle of strips and repeat the Quality Control procedure.

Each dialysis facility should determine the frequency of testing and the optimal procedures for its own Quality Control Program.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the Serim GUARDIAN RESIDUAL CHLORINE Test Strips are based on analytical studies using samples yielding a range of chlorine levels. Amperometric titration was used as the reference method for measuring chlorine levels.[5]

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 one color block of the reference value. In blind studies, concentrations of 0.25 ppm have been read as less than 0.5 ppm, and concentrations of 1.0 ppm as greater than 0.5 ppm in all cases.

LIMITATIONS

Serim GUARDIAN RESIDUAL CHLORINE Test Strips will give a positive result with any substance which will oxidize the indicator directly or which will oxidize iodide to iodine under neutral pH conditions. These substances include, among others, hypochlorite, chlorine, monochloramine, nitrogen trichloride, ozone, iodine, bromine and peroxide. Serim GUARDIAN RESIDUAL CHLORINE **Test Strips are not suitable for testing for chlorine in bicarbonate concentrates or dialysate.**

The indicator does not react with many of the substances found in non-purified water such as sulfate, nitrate, chloride, copper, calcium and magnesium. Manganese (IV) and iron (III) give false positive results, while the presence of nitrite will yield a false negative. However, since rinsing of hemodialysis systems is usually done with highly purified water or saline, it is unlikely that these potentially interfering substances will appear in the rinse solution.

REFERENCES

[1] American National Standard, Hemodialysis Systems (ANSI/AAMI RD5-1992) (Association for the Advancement of Medical Instrumentation, Arlington, VA, 1995).
[2] C. Sorber, W. Cooper and E. Meier, "Selection of 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.
[3] R. Bauer, B.F. Phillips and C.O. Rupe, "A Simple Test for Estimating Free Chlorine," Journal AWWA (November 1972), pp. 787-789.
[4] J. Liebermann, 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.
[5] "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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