

Serim[®]

GUARDIAN[™]

RESIDUAL PEROXIDE

Test for residual peroxide
in rinse solution

DESCRIPTION

Serim[®] GUARDIAN[™] RESIDUAL PEROXIDE Test Strips (Product Code 5105) provide a convenient means for measuring the concentration of peroxide remaining in dialysate lines and dialyzers after disinfection with peracetic acid/peroxide-based disinfectants (such as Renalin[®] 100, Actril[®], Minncare[®]1, Puristeril[™]340², PERACIDIN[®]3, PerAldecide[™]4, and Micro-X[®]5).

Because concentrations of peracetic acid are much lower than hydrogen peroxide levels, specific measurement of peroxide gives an estimate of the total residue.

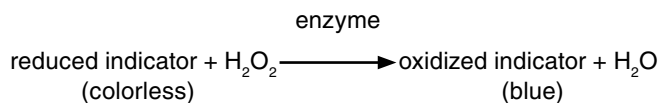
A rapid screening method will detect levels of peroxide at and above 1 ppm and a 15 second semi-quantitative method allows estimation of concentrations between 0 and 10 ppm.

The qualitative rapid screening method can be used to determine that the disinfectant has been adequately rinsed from the machine. The semi-quantitative method should be used if any color is apparent after using the qualitative procedure. Further, the semi-quantitative method may be useful when establishing the adequacy of the rinse times. Refer to the dialyzer manufacturers' product insert for recommendations on proper rinse procedures.

Results of 3 ppm and above indicate that further rinsing is required.

CHEMICAL PRINCIPLES OF THE TEST

Serim GUARDIAN RESIDUAL PEROXIDE Test Strips react with peroxide to form a blue color. The test is buffered to a pH of 7.0 and contains an enzyme and an indicator. The indicator, in the presence of the enzyme, is oxidized rapidly by hydrogen peroxide. The intensity of the blue color is proportional to the concentration of peroxide present in the dialysate rinse.



WARNINGS AND PRECAUTIONS

- Keep all unused test strips in the original bottle.
- Do not remove the desiccant pack.
- Replace the cap immediately and tightly after removing a test strip; the strips must be protected from humidity.
- Do not touch the indicator pad.
- Do not allow the indicator pad to come into contact with liquids or with work surfaces which may be contaminated with potentially interfering substances.
- Serim GUARDIAN RESIDUAL PEROXIDE Test Strips are intended only for testing residual levels of peracetic acid/peroxide-based disinfectants following a rinse procedure. To test for potency of the disinfectant, use Serim GUARDIAN PERACETIC ACID Test Strips. Contact Serim or an authorized dealer for availability.
- This is a single use device. After use, discard the test strip according to federal, state and local regulations.

STORAGE

- The Serim GUARDIAN RESIDUAL PEROXIDE 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 printed on bottom of bottle.

DIRECTIONS

Testing may be done from any convenient port where the rinse solution has passed through the dialyzer or dialysate lines.

For Qualitative Results:

1. Immerse the indicator pad into the rinse solution for two (2) seconds.
2. Shake off excess sample.
3. If no color is immediately apparent, the hydrogen peroxide is less than 1 ppm and further rinsing is not required.

For Semi-Quantitative Results:

1. Immerse the indicator pad into the rinse solution for two (2) seconds.
2. Shake off excess sample.
3. Fifteen (15) seconds after withdrawal from the sample, compare the color of indicator pad to the color chart on the bottle label.
4. Record the results.

RESULTS

The concentration of hydrogen peroxide in rinse solution is obtained by comparing the color of the indicator pad with color blocks on the bottle label. Concentrations which fall between color block values can be estimated.

NOTE: Tan/brown colors may develop at peroxide concentrations above 20 ppm.

The color blocks are calibrated in terms of hydrogen peroxide concentration in parts per million (ppm). Color blocks are designated as 0 ppm, 1 ppm (1mg/L), 3 ppm (3 mg/L), 5 ppm (5 mg/L) and 10 ppm (10 mg/L) peroxide.

QUALITY CONTROL

Each facility should determine the frequency of testing and the optimal procedures for its own Quality Control Program. The regular use of procedures using 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.

PERFORMANCE CHARACTERISTICS

The performance characteristics of Serim GUARDIAN RESIDUAL PEROXIDE Test Strips are based on analytical studies using samples to which either hydrogen peroxide or peroxide/peracetic acid was added to give a range of peroxide levels. Peroxide/peracetic acid levels were standardized with a colorimetric method⁶ which had been validated against a standard titrimetric method.⁷

Data in the table below summarize Blind Study Results obtained on three different lots of product by 4 readers recording 12 replicates at each standard level.

BLIND STUDY RESULTS

Peroxide Concentration	100% of Readings were within:
0 ppm	0 ppm
1 ppm	1-3 ppm
3 ppm	3-5 ppm
5 ppm	3-10 ppm
10 ppm	5-10 ppm

Sensitivity and accuracy of the test depend on variability in color perception, lighting conditions and the possible presence of interfering substances.

The lowest detectable level of peroxide is about 1.0 ppm.

LIMITATIONS

The Serim GUARDIAN RESIDUAL PEROXIDE Test Strips will react with any substance which will oxidize the indicator directly. Such strong oxidants should not be present in the rinse solution. Ascorbic acid in concentrations as low as 3 ppm will interfere with the reaction in the indicator pad. Much of this interference is due to the fact that ascorbate reduces the peroxide and effectively lowers its concentration in the sample.

Serim GUARDIAN RESIDUAL PEROXIDE Test Strips are sensitive to levels of peroxide at approximately 1.0 ppm.

REFERENCES

- ¹ Renalin 100 Cold Sterilant, Actril Cold Sterilant and Minncare Cold Sterilant are registered trademarks of MEDIVATORS Renal Systems Group. Serim Research Corporation has no relationship with, nor endorsement from MEDIVATORS Inc.
- ² Puristeril 340 is a registered trademark of Fresenius USA, Inc.
- ³ Peracidin is a registered trademark of Alcavis HDC LLC.
- ⁴ PerAldecide is a trademark of Alden, a division of Metrex.
- ⁵ Micro-X is a registered trademark of Reprocessing Products Corporation. (RPC)
- ⁶ Colorimetric method. J. E. Frew, P. Jones and G. Scholes. "Spectrophotometric Determination of Hydrogen Peroxide and Organic Hydroperoxides at Low Concentrations in Aqueous Solution." *Analytica Chimica Acta* 155 (1983) 139-150.
- ⁷ Titrimetric method. A.O.A.C. Method 32.069(d), 13th Edition, 1980.



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