

DESCRIPTION

SteriChek Peracetic Acid Reagent Strips provide a convenient, accurate means of measuring the concentration of peracetic acid in dialyzer reprocessing. Dialyzer samples for testing require no dilution or mixing. As a measure of safety, concentrations below 500 ppm (mg/l) will test negative and concentrations of 700 ppm and higher will test positive with SteriChek Peracetic Acid Reagent Strips. Peracetic acid is the primary active ingredient in Renalin® Dialyzer Reprocessing Concentrate.¹ By testing dialyzers after storage with Renalin disinfectant, a positive reaction for peracetic acid will indicate a level of 500 ppm or greater is present.

Concentrations as low as 500 ppm have been proven to qualify as a sterilant.¹

The performance characteristics of SteriChek Peracetic Acid Reagent Strips are based on analytical studies using samples to which either peracetic acid or Renalin Dialyzer Reprocessing Concentrate was added to give a range of peracetic acid concentrations. A titrimetric procedure was used as the reference method.²

⚠ WARNING

- **SteriChek Peracetic Acid Reagent Strips are not designed to determine if disinfectant levels are safe. Use the strips only before rinsing the dialyzer.**
- **Keep all unused strips in the original bottle. Do not remove dessicant pack. Replace cap tightly immediately and tightly after removing a strip; the strips must be protected from heat and humidity.**
- **Do not touch the reagent pad area. Do not allow the pad to come into contact with liquids or with work surfaces, as these may be contaminated with potentially interfering substances.**

DIRECTIONS

If the strips are not taken directly from bottle and immersed in sample, keep strips on an uncontaminated paper towel until use.

1. Remove the dialysate port cap prior to rinsing dialyzer.
2. Collect sample in port cap sufficient to cover test area on strip.
3. Immerse test area on strip in the dialysate port cap for one second.
4. Shake off excess sample.
5. Empty and replace port cap.

6. Read results within 10 seconds after immersion:
 - If test area is gray/purple or black, peracetic acid presence is confirmed.
 - Disregard any color changes that take place more than 10 seconds after withdrawal from sample.**Note:** Use strips only prior to rinsing dialyzer.

For Quality Control:

Each facility should determine its own quality control procedure. Testing and recording test strip results with the control solution (see below) provides the user with a warning of a possible test strip error, potential use of outdated test strips, or of improperly stored or handled test strips.

Preparation of the Control Solution:

Renalin® Dialyzer Reprocessing Concentrate that is fresh and diluted 1:50 with water will provide a positive reaction with SteriChek Peracetic Acid Reagent Strips. A mixture that consists of one part of this dilution and two parts water will provide a negative result.

STORAGE

The SteriChek Peracetic Acid Reagent Strips must be kept in the original bottle with the lid tightly closed to obtain the best results. Do not remove the desiccant pack. Store at temperatures between 60° - 90°F (16° - 32°C). Use within 6 months after first opening bottle. Do not use the test strips (from an opened or unopened bottle) after the expiration date.

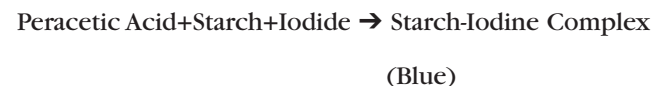
RESULTS

Peracetic acid concentrations below 500 ppm (mg/l) will not produce sufficient color change on the test area when strips are read at 10 seconds after immersion. Immediate color change may occur after immersion, but will fade to light yellow by 10 seconds after testing sample. The test area at 500 ppm may sporadically display a gray, gray/purple, or “mottled” color at a 10-second reading. As the concentration of peracetic acid approaches 700-800 ppm, the color displayed on strip may appear gray/purple or black. At 700 ppm or greater, the test area will show gray/purple or black color development. Disregard any color changes that take place more than 10 seconds after withdrawal from sample.

CHEMICAL PROPERTIES OF THE TEST

The oxidation of iodide to iodine by peracetic acid is the basis for this test.² Iodine forms a dark complex in the presence of starch. The test area contains a reducing agent at an amount equal to 500 ppm peracetic acid. At peracetic acid concentrations below 500 ppm iodine is reduced back to iodide by the reducing agent, preventing the formation of the

dark starch-iodine complex. At greater concentrations of peracetic acid, there is not enough reducing agent to reduce all the iodine, and the dark blue starch-iodine complex is formed. The color appears gray/purple or black on the light yellow background of the test.



PERFORMANCE CHARACTERISTICS

SteriChek Peracetic Acid Reagent Strips' performance characteristics are generated from sample studies where peracetic acid or Renalin Dialyzer Reprocessing Concentrate were added to provide a peracetic acid concentration range. The reference method was a titrimetric procedure.² In 100 observations with 10 readers, peracetic acid concentrations of 500 ppm (mg/l) and 700 ppm were accurately assessed as negative and positive, respectively.

LIMITATIONS

- SteriChek Peracetic Acid Reagent Strips are more reactive to peracetic acid than hydrogen peroxide. Peroxide color may develop slowly past the 10-second reading time.
- False positive readings may be caused by strong oxidants in sufficient concentration. However, since rinsing of hemodialysis systems is usually done with highly purified water, it is unlikely that these potentially interfering substances will appear in the rinse water.
- False negatives may occur from reducing agents such as ascorbic acid.

AVAILABILITY

Product 811906 SteriChek Peracetic Acid Reagent Test Strips contains six bottles of 100 Peracetic Acid Reagent Strips and a multilingual product insert. Also enclosed for your use are color-coded stickers that correspond to the color of the bottle label and kit box label. These stickers may be applied on the top of each bottle for easy product identification. Each sticker includes a space to record the date the bottle is opened.

These SteriChek testing products are also available from your distributor:

811900	Residual Chlorine Reagent Strips
811902	0.1 ppm Total Chlorine DPD Kit
811903	0.1 ppm Total Chlorine DPD Refill Kit
811905	Residual Peroxide Reagent Strips
811909	Sensitive 0.1 ppm Total Chloramines and Residual Chlorine Reagent Strips
811911	Sensitive 5 ppm Low-Range Hardness Strips
811912	Chlorine Control Tablets
811913	Residual Peroxide Control Tablets
811916	Bicarb pH Reagent Strips
812014	Blood Leak Reagent Strips

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