Serim®

GUARDIAN™

PERACETIC ACID

Test for peracetic acid potency in dialyzer reuse

DESCRIPTION

SERIM® GUARDIAN™ PERACETIC ACID Test Strips (Product Code 5106) provide a rapid, convenient means of indicating the concentration of peracetic acid in dialyzer reprocessing concentrates such as Renalin® Cold Sterilant, PerAldecide™, Puristeril® 340, Peracidin™ and Micro-X®.

Samples of the peracetic acid disinfectant may be tested without dilution or mixing steps. Concentrations of peracetic acid at or below 400 ppm will "FAIL" and concentrations at or above 800 ppm will "PASS" with **SERIM GUARDIAN PERACETIC ACID** Test Strips.

CHEMICAL PRINCIPLES OF THE TEST

The test is based on the oxidation of iodide to iodine by peracetic acid.[1] Iodine in the presence of starch forms a dark-colored complex.

A reducing agent in the indicator pad inhibits color development. When the peracetic acid concentration is sufficient to overwhelm the reducing agent, the excess oxidizes the iodide resulting in the formation of a blue or black color.

Peracetic Acid + Starch + Iodide ⟶ Starch-Iodine Complex (Blue)

WARNINGS AND PRECAUTIONS

- **Serim GUARDIAN PERACETIC ACID** Test Strips are intended only for testing potency of Peracetic Acid in dialyzer reprocessing concentrates. For residual testing, use **Serim GUARDIAN RESIDUAL PEROXIDE** Test Strips (Product Code 5105).
- Always test prior to rinsing the dialyzer.
- Keep all unused 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 indicator pad to come into contact with liquids or with work surfaces which may be contaminated with potentially interfering substances.
- Do not leave the bottle or individual strips laying on the dialysis machine as heat from the machine will degrade the reactivity of the strips.

STORAGE

- **SERIM GUARDIAN PERACETIC ACID** 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

1. Prior to rinsing the dialyzer, collect a sample of the peracetic acid disinfectant in the dialyzer port cap sufficient to completely immerse the indicator pad on the test strip. (Do not dilute sample.)
2. Immerse indicator pad into sample for one second, then remove strip.
3. Immediately shake the strip to remove excess sample.
4. Exactly 10 seconds after withdrawal from the peracetic acid sample, observe the color of the indicator pad and interpret according to the RESULTS below.
5. Empty remaining sample into an appropriate waste container and replace the port cap on the dialyzer.

Note: Do not reuse the sample for more than two test strips.

RESULTS

If the indicator pad is predominantly or entirely white, record the result as "FAIL"; the peracetic acid concentration is at or below 400 ppm.

If the indicator pad is predominantly or entirely gray/blue, black or brown, record the result as "PASS"; the peracetic acid concentration is at or above 800 ppm.

Note: Ignore any color changes that occur after ten seconds.

QUALITY CONTROL

The table below indicates the approximate ratio of fresh, undiluted peracetic acid disinfectant and water required to prepare Positive and Negative Peracetic Acid Control Solutions. These solutions can be used as samples following the steps under the "DIRECTIONS" portion of this insert.

Disinfectant Brand Name	Positive Control Solution	Negative Control Solution
	Ratio of Undiluted Disinfectant to Water (mL)	Ratio of Undiluted Disinfectant to Water (mL)
Renalin®	1:50	1:100
Puristeril® 340	1:40	1:160
Peracidin™	1:50	1:100
Micro-X®	1:50	1:100

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 is deteriorated due to improper storage or handling. If results with the Quality Control Solutions are not as expected, do not use that particular bottle of Serim GUARDIAN PERACETIC ACID Test Strips. Retain the bottle and any remaining strips and call Serim at 1-800-542-4670 or your local Serim dealer. Open a new bottle of strips and repeat the QC procedure.

PERFORMANCE CHARACTERISTICS

The performance characteristics of Serim GUARDIAN PERACETIC ACID Test Strips are based on analytical studies using samples to which peracetic acid was added to give a range of peracetic acid concentrations. A titrimetric procedure was used as the reference method.[1]

Peracetic Acid Concentration	% Results Read as Positive
400 ppm	0%
600 ppm	70%
800 ppm	100%

In 972 observations by six different readers using 3 lots of strips, peracetic acid concentrations of 400 ppm and 800 ppm were correctly classified as negative and positive, respectively.

LIMITATIONS

It is important to observe the Serim GUARDIAN PERACETIC ACID Test Strips at exactly the ten second read time because peroxide-generated color development may take place slowly over time. Ignore color changes that occur after 10 seconds.

Other strong oxidants in sufficient concentrations may cause false positive results, i.e., chlorine at about 800 ppm. Reducing agents such as ascorbic acid may cause false negatives. However, it is unlikely that these interfering substances will be present since highly purified water is used throughout dialyzer reprocessing.

REFERENCES

[1] F.P. Greenspan and D.G. Mackellar. Analytical Chemistry (1948) 20:1061.

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