



# RESIDUAL FORMALDEHYDE

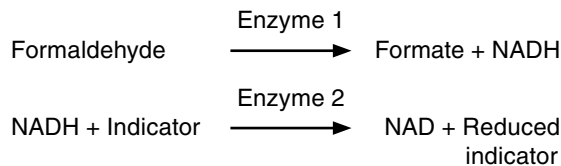
Test for residual formaldehyde in rinse solution

## DESCRIPTION

Serim® RESIDUAL FORMALDEHYDE Test Strips (Product Code 5112) provide a convenient means of measuring the concentration of formaldehyde remaining after rinsing dialyzers or dialysate lines prior to use in hemodialysis. The Association for Advancement of Medical Instrumentation recommends residual formaldehyde concentrations below 3 ppm.<sup>1</sup> With proper storage and handling, routine quality control, and strict adherence to the directions for use, Serim RESIDUAL FORMALDEHYDE Test Strips can reliably detect concentrations below 3 ppm.

## CHEMICAL PRINCIPLES OF THE TEST

Serim RESIDUAL FORMALDEHYDE Test Strips have a matrix impregnated with two enzymes which, specifically in the presence of formaldehyde, react sequentially to reduce the indicator. The intensity of pink color generated in the presence of formaldehyde is related to the concentration.



Comparison of the color of the reacted indicator pad to the color chart on the bottle label provides an estimate of the concentration of formaldehyde.

## 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.
- Do not expose the test strips to formaldehyde vapors.
- Serim RESIDUAL FORMALDEHYDE Test Strips are not appropriate for use with samples containing formaldehyde at high concentrations.

- Serim RESIDUAL FORMALDEHYDE Test Strips are intended only for testing **residual** levels of formaldehyde following a rinse procedure.
- This is a **single use device**. After use, discard the test strip according to federal, state and local regulations.

## STORAGE

- Unopened bottles of Serim RESIDUAL FORMALDEHYDE Test Strips **must be refrigerated** until needed.
- Allow the unopened bottle to come to 59°–86°F (15°–30°C) before opening.
- After opening, store at room temperature (15°–30°C or 59°–86°F) in the original bottle with the lid tightly closed.
- Do not place the bottle of test strips or individual test strips on the dialysis delivery machine, as the heat will alter the chemical activity of the test strips.
- 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.
- Do not remove the desiccant pack.

**IMPORTANT: PROTECTION AGAINST MOISTURE AND HEAT IS ESSENTIAL TO GUARD AGAINST ALTERED CHEMICAL REACTIVITY.** Discoloration or darkening of indicator pad may indicate deterioration. If this is evident or if test results are questionable or inconsistent with expected findings, the following steps are recommended:

1. Confirm that the product is within expiration date shown on the bottom of the bottle.
2. Test a strip in formaldehyde free, deionized water. If the color is darker than the “trace” color block, discard remaining strips and open a new bottle.
3. Retest with a freshly opened bottle of test strips.

If proper results are not obtained, call 1-800-542-4670 or 574-264-3440 or contact your local Serim dealer for advice on testing technique and results.

## DIRECTIONS

It is very important that the directions for use be followed carefully to ensure accurate results.

1. Dispense\* one rounded drop of sample onto the indicator pad. Start timer.
2. Carefully place the strip on a clean dry paper towel allowing the rounded drop of sample to remain on the pad for 2 minutes.
3. Two minutes after application of the sample, drain the excess sample from the indicator pad by touching the side edge of the strip to a paper towel.
4. Compare the color on the indicator pad to the color chart on the bottle.

\*The sample to be tested may be obtained in the same manner as for a Schiff test. In dialyzer reuse, rather than collecting the sample in a syringe, it may be preferable to carefully break the recirculating saline line. If testing is done at the drain, pass the indicator pad on the strip quickly (one second or less) through the rinse stream to collect a

rounded drop. Do not run large volumes of the sample over the indicator pad or leave in the rinse stream for more than one second as active ingredients may be washed from the indicator pad.

**Note:**

- Do not run large volumes of sample over the indicator pad.
- Comparing the color **before** 2 minutes will give falsely low results.
- If the rounded drop is removed from the indicator pad before the 2-minute reaction period ends, rerun the test.
- **Dipping** strips into a sample solution can give falsely low readings.

**RESULTS**

The concentration of formaldehyde is obtained by comparing the color of the indicator pad to the color chart on the bottle label. The color blocks are designated as 0, Trace, 2.5 and 5 ppm.

To assure that concentrations are less than 3 ppm, color development on the indicator pad must be equal to or lighter than the 2.5 ppm color block on the bottle label.

**PERFORMANCE CHARACTERISTICS**

The analytical performance of Serim RESIDUAL FORMALDEHYDE Test Strips was evaluated with solutions diluted volumetrically in water from a formaldehyde stock solution whose concentration was determined titrimetrically.<sup>2</sup>

Performance data was obtained in blind studies using a panel of 4 different readers and 9 different product lots. Collective data represented 756 readings per standard level. Statistics from this data are presented below:

Readings (ppm)	
Formaldehyde Standard (ppm)	Average Formaldehyde Concentration (ppm)
0	0
2.5	2.8
5.0	5.0

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

**LIMITATIONS**

- Serim RESIDUAL FORMALDEHYDE Test Strips are suitable for testing residual levels of formaldehyde in the approximate range of 0–5 ppm.
- Do not use these strips to test for aldehydes other than formaldehyde.
- Samples containing more than 0.05 mg ascorbate/mL will give falsely elevated readings.
- Samples with pH below 6.5 can suppress color development and give falsely low formaldehyde readings.
- The following disinfectants inhibit color development and will give erroneously low results if present in samples above the indicated levels:

Chlorine . . . . .50 ppm  
 Hydrogen Peroxide . . . . .1000 ppm  
 Glutaraldehyde . . . . .20 ppm

**REFERENCES**

<sup>1</sup> AAMI Standards; Dialysis 2011 Edition. ANSI/AAMI RD47:2008 Reprocessing of Hemodialyzers. Association for the Advancement of Medical Instrumentation, Arlington, VA.  
<sup>2</sup> J.F. Walker "Quantitative Analysis of Formaldehyde" *Formaldehyde*, 3rd Ed. J.F. Walker (Reinhold Publishing Corp., New York, N.Y., 1964) pp. 486– 488.



© 2013 Serim Research Corporation  
 P.O. Box 4002, Elkhart, IN 46514-0002  
 Tel: (800) 542-4670 · FAX: (574) 266-6222  
 Tel: (574) 264-3440  
 E-mail: customerservice@serim.com  
 Web site: www.serim.com