

PRODUCT PROFILE

Serim[®] RESIDUAL FORMALDEHYDE TEST STRIPS

WHAT does this product do?

Serim Residual Formaldehyde Test Strips give a semi-quantitative indication of the concentration of formaldehyde remaining after rinsing formaldehyde disinfectant from dialyzers, dialysis delivery machines, water systems or portable reverse osmosis (RO) machines.

WHY should I use this product?

If formaldehyde is not thoroughly rinsed from the dialyzer, the patient will complain of burning and itching at the vascular access site.¹ Chronic exposure to formaldehyde can cause the formation of anti-N erythrocyte antibodies, which has been associated with hemolysis of the red blood cells.^{1,2}

AAMI recommends the residual concentration of formaldehyde be reduced to below 3 ppm.^{2,3}

WHERE do I use this product?

Use Serim Residual Formaldehyde Test Strips to test rinse solution from any convenient port after the solution has passed through the dialyzer. Test a sample of rinse solution from the drain or from the post-dialyzer recirculating line of the hemodialysis delivery system.



Follow the RO manufacturer's instructions for collecting and testing samples from RO machines and water systems after disinfecting with formaldehyde.

WHEN do I use this product?

For reused dialyzers, it is important to test each dialyzer immediately before use to ensure that the disinfectant was adequately rinsed⁴. Whenever the dialysis delivery machine, RO machine or water system is disinfected with formaldehyde, use Serim Residual Formaldehyde Test Strips to ensure complete rinse-out of the disinfectant.

HOW do I use this product?

Serim Residual Formaldehyde Test Strips are supplied in ready-to-use form. When placed in contact with the sample according to the directions for use (see below), the indicator pad changes color relative to the concentration of formaldehyde present in the rinse solution.

Ordering Information

Serim Residual Formaldehyde Test Strips: Product Code 5112 – sold in individual bottles containing 100 strips

Test Method	Syringe or Recirculating Line	Stream from Drain
Sample	Dispense 1 rounded drop of rinse solution onto the indicator pad using a syringe or by breaking the recirculating saline line.	Collect 1 rounded drop of rinse solution on the indicator pad by passing the strip quickly (1 second) through the rinse stream.
Test Strip Technique	Allow the sample to remain on the indicator pad for 2 minutes, and then blot the side edge of the pad on a paper towel.	
Semi-quantitative Results	Compare the color of the indicator pad to the color blocks on the bottle label.	

Serim Residual Formaldehyde Test Strips *must be refrigerated* until needed.
Allow the bottle of strips to come to room temperature prior to opening or use.
The lot number and expiration date are printed on the bottom of each bottle.

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Features	Benefits
Ready-to-use strips	<ul style="list-style-type: none"> No preparation or mixing of reagents No glass vials or sharps needed, eliminates needlestick hazard No syringe needed to inject sample as required by Schiff's Reagent ampoule tests Extra safety and cost savings
Quick, semi-quantitative results in 2 minutes	<ul style="list-style-type: none"> Allows quick initiation of dialysis procedure
Test is sensitive to 1 ppm	<ul style="list-style-type: none"> Provides an extra margin of safety
Reliably detects residual formaldehyde in water	<ul style="list-style-type: none"> Meets the AAMI-recommended concentration of less than 3 ppm residual formaldehyde in rinse water from dialyzers, dialysis machines or water systems/equipment disinfected with formaldehyde Superior performance to traditional "off-label chlorine tests such as CliniTest® Tablets* which cannot detect formaldehyde until potentially harmful concentrations of 80 ppm or more are present⁵
Simple to interpret color blocks	<ul style="list-style-type: none"> Accurate and consistent results minimize variation between readers Color of indicator pad is directly compared to color blocks on bottle label
Simple procedure	<ul style="list-style-type: none"> Quick and reliable method determines disinfectant is below the target concentration No calculations or "drop counting" needed
Labeled for dialysis use ⁵	<ul style="list-style-type: none"> No need to qualify an "off-label" test for dialysis use No need to monitor changes in product performance from lot-to-lot
Sample can be dispensed onto indicator pad or strip can be held in rinse stream	<ul style="list-style-type: none"> Maximum convenience for user, no matter where a proper sample is most easily obtained
Consistent color reactions	<ul style="list-style-type: none"> Results not affected by aging throughout shelf life of the product
Each bottle clearly labeled with: <ul style="list-style-type: none"> Lot number Expiration date 	<ul style="list-style-type: none"> Traceability of product from manufacturing to final user Leaves no doubt as to the age or integrity of the product

*CliniTest® Tablets are a registered trademark of Siemens Healthcare Diagnostics Inc.

References:

- Handbook of Dialysis, Third Edition, pg 175. JT Daugirdas, PG Blake, TS Ing. Lippincott, Williams and Wilkins
- AAMI Standards and Recommended Practices, Dialysis, 2008 Edition, RD47:2008 *Reprocessing of dialyzers*. Association for the Advancement of Medical Instrumentation. Arlington, Virginia.
- Proper Mechanisms for Assuring Disinfectant Concentrations for Use in Hemodialysis, Nephrology News & Issues, June 1999, pg 18-27.
- Handbook of Dialysis, Third Edition, pg 173. JT Daugirdas, PG Blake, TS Ing. Lippincott, Williams and Wilkins
- Proper mechanisms for assuring disinfectant concentrations for use in hemodialysis*. Nephrol News Issues. 1999 Jun;13(6):18, 23, 27. Arduino MJ.

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