



**Reprocessing Products Corp (RPC)**  
Rabrenco Scientific – Division of RPC

**1-2% Formaldehyde Test Strips - K100 0108**  
For Use in Testing Potency of 1-2% Formaldehyde Disinfectant  
Carefully Read Instructions for Use

Manufactured for:  
Reprocessing Products Corp (RPC)  
Tucson, AZ 85705 PH: 800-647-3873

Reorder No. K100 0108  
Quantity – 100 per bottle

*RPC 1-2% Formaldehyde Test Strips provide a semi-quantitative method of estimating the concentration of formaldehyde used in disinfecting dialyzers and reverse osmosis (RO) systems. The test strips can be used to determine formaldehyde concentrations between 1% and 2%.*

*The tests are not intended to replace microbiological tests or quantitative analysis of stock solutions of formaldehyde.*

### **Warnings and Precautions**

- Do not use this product to determine that rinsing procedures are adequate to bring the formaldehyde concentration to safe residual levels. (Refer to the “**Limitations**” section of this insert.) For detecting residual concentrations (3-5 ppm) of formaldehyde in rinse water, use RPC Residual Formaldehyde Test Strips, Reorder No. K100 0107.
- RPC Formaldehyde Test Strips cannot be used to determine formaldehyde concentrations less than 1%.
- Do not use this test to determine glutaraldehyde concentrations.
- Care should always be taken to avoid mixing strong acids or bases with formaldehyde.

### **Storage**

- Store at temperatures between 15° - 30°C (59° - 86°F).
- Do not remove the desiccant pack.
- Keep all unused strips in the original bottle.
- Replace cap immediately and tightly after removing a strip; the strips must be protected from humidity.
- Use within 3 months from the date the bottle was opened. Always write the “Date Opened” in the space provided on the bottle label.
- Do not touch the indicator pad area.
- Do not allow the pad to come in contact with liquids or with work surfaces that may be contaminated with interfering substances.
- Do not leave strips outside the bottle in areas exposed to formaldehyde vapors.
- Do not leave the bottle or individual strips lying on the dialysis machine, as the heat from the machine will degrade the reactivity of the strips.
- Do not use test strips (from an opened or unopened bottle) after the expiration date.

### **Instructions for Use**

1. Either immerse indicator pad into the sample for **one second** or dispense one drop from syringe onto the indicator pad. (Do **not** dispense large volumes of sample over the indicator pad as active ingredients may be washed from the pad).
2. Immediately remove excess sample from the indicator pad by touching the side edge of the strip to a paper towel.
3. Wait 90 seconds and compare the color of the indicator pad to the color chart on the bottle label.

### **Results**

The concentration of formaldehyde in the sample is obtained by comparing the color of the reacted indicator pad with the color blocks on the bottle label. RPC 1-2% Formaldehyde Test Strip color blocks are designated “less than 0.4%”, “1%” and “2%”.

A result matching the “less than 0.4%” color block indicates that the formaldehyde concentration is **below** 0.4% but not necessarily zero. The **lowest concentration of formaldehyde** that the RPC 1-2% Formaldehyde Test Strip can **reliably detect is approximately 1%**, as depicted by the center color block. At concentrations near 2%, the indicator pad turns tan/beige in color. The indicator pad will develop a yellow color at formaldehyde concentrations **above** 2%.

## Performance Characteristics

RPC 1-2% Formaldehyde Test Strips can reliably detect formaldehyde at a concentration of *approximately* 1%. The performance characteristics of the test strips are based on analytical studies using samples of formaldehyde solutions of various concentrations. The reference method<sup>1</sup> for determination of formaldehyde concentrations in these samples was based on the reaction of formaldehyde with sodium sulfite followed by titration of the released sodium hydroxide.

Reference Value	Reader Interpretation	
	Mean (%)	Std. Dev.
0 %	0	0
1 %	1.0	0.06
2 %	2.0	0

Correlation coefficient: 0.920       $y = 1.063x + .035$

The sensitivity and accuracy of the test strip depends on several factors including variability in the user's color perception, variation in lighting conditions, and the possible presence of interfering substances.

## Limitations

The AAMI-suggested maximum concentration for residual formaldehyde in dialyzer re-use is 5 ppm. (Some state regulations require levels below 3 ppm<sup>2</sup>). RPC 1-2% Formaldehyde Test Strips can reliably detect formaldehyde concentrations only as low as *approximately* 1% (or 10,000 ppm of formaldehyde); therefore these strips **cannot** be used to detect residual concentrations of formaldehyde. [For detecting residual concentrations of formaldehyde in rinse water, use RPC Residual Formaldehyde Test Strips, Reorder No. K100 0107.]

The RPC 1-2% Formaldehyde Test Strips should only be used to determine formaldehyde concentrations between 1% and 2%. These strips **cannot** be used to determine formaldehyde concentrations less than 1%.

RPC 1-2% Formaldehyde Test Strips will react with any substance containing active aldehydes in sufficient quantities.

The test will give "false positives" in solutions of low pH and "false negatives" in solutions of high pH. Treated water used to dilute concentrated formaldehyde will not ordinarily have sufficient pH variations to affect the test.

## References

<sup>1</sup>Formaldehyde reference method: J.F. Walker "Quantitative Analysis of Formaldehyde" *Formaldehyde*, 3rd Ed. J.F. Walker (Reinhold Publishing Corp., New York, N.Y., 1964) pp. 486-488.

<sup>2</sup>AAMI – Association for the Advancement of Medical Instrumentation, 2001 Edition, *Dialysis* (ANSI/AAMI RD47-1993), pg. 157 and pg. 166.