

# PERASSAY® 500 PERACETIC ACID TEST STRIPS - 78378-000

## Instructions for Storage and Use - Package Insert

### INTRODUCTION

Perassay 500 Peracetic Acid Test Strips provide an easy, rapid and convenient means of determining levels of peracetic acid. The test is designed to indicate peracetic acid in concentrations of 500 ppm or greater. Peracetic acid concentrations of 500 ppm or greater test positive, and concentrations lower than 500 ppm test negative. Peracetic acid is one of the active ingredients in Renalin Cold Sterilant<sup>1</sup>. Concentrations as low as 500 ppm peracetic acid have been shown to act as a sterilant<sup>1</sup>. By using the Perassay 500 test strips to test dialyzers after storage with Renalin, a positive reaction for peracetic acid will ensure that a level above 500 ppm is present. Samples may be tested without dilution or mixing steps.

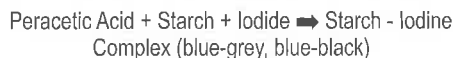
Perassay 500 Peracetic Acid Test Strips are available in vials of 100 reagent strips each.

### WARNINGS AND PRECAUTIONS

- Store all unused test strips in their original vial.
- Replace cap immediately and firmly after removing a strip.
- Use only to determine levels of peracetic acid prior to rinsing.
- Do not measure residual peracetic acid levels with these strips.
- Avoid touching or exposing the reagent pad area to foreign liquids, dirt or any potentially interfering substances.
- Do not use test strips after the expiration date.

### CHEMICAL PRINCIPLES OF THE TEST

The chemical reaction that takes place on the Perassay 500 test strip is the oxidation of iodide to iodine with starch as the indicator<sup>2</sup>. The reaction is as follows:



### PERFORMANCE CHARACTERISTICS

A study was performed on three separate lots of Perassay Peracetic Acid Test Strips in varying concentrations of Renalin. The strips were tested immediately after opening, and at one month after opening. Split samples were used with 5 replicates for each data point. The test was performed under simulated use conditions. The results showed all strips gave positive results at concentrations of 500 ppm peracetic acid or higher, and negative results at concentrations less than 500 ppm.

### QUALITY CONTROL

A dilution of fresh Renalin (5 ± 1% peracetic acid) can be used as a quality control to verify the functionality of the test strips. Depending on the concentration of peracetic acid, one part Renalin diluted with 50 parts water (50:1) will provide a solution containing 800 to 1200 ppm peracetic acid. This solution will produce a positive reaction. A further dilution with three parts water (3:1) will provide a solution containing 200 to

### STORAGE

Store the Perassay 500 Peracetic Acid Test Strip container in a cool dry environment. Once opened store at room temperature. Do not refrigerate. Replace cap immediately and firmly after removing a strip. Store all unused test strips in the original vial. Do not use test strips after the expiration date (see vial label).

### DIRECTIONS

Open vial and remove the number of test strips to be used. Place the strips on a clean paper towel where they will not be contaminated. Replace the cap firmly on the container of the remaining test strips. Before rinsing the dialyzer, remove a dialyzer port cap and collect at least 1 mL of solution. Dip the test strip into the sample, immersing the entire reaction pad. Remove the test strip and gently shake off any excess liquid. Within 10 seconds, note the entire reaction pad color development.

Blue-gray and blue-black color **over the entire reaction pad** within 2 to 5 seconds, and which does not fade, indicates peracetic acid levels of 500 ppm (mg/L) or greater.

No color development, scattered spots of blue-gray or blue-black or brown, or immediate fading of blue-gray or blue-black, indicates peracetic acid levels of less than 500 ppm (mg/L).

**NOTE:** The reaction pad may slowly change or develop color after the initial reaction. This is normal and should be ignored for the purpose of test interpretation. Disregard any color changes after the initial 10 seconds.

**NOTE:** Failure to follow directions for use may result in patient injury.

300 ppm peracetic acid. This solution will produce a negative reaction.

### RESULTS

Peracetic acid concentrations less than 500 ppm will not produce color on the entire reagent pad within 10 seconds after exposure. Concentrations greater than 500 ppm will produce a blue-grey or blue-black color over the entire strip.

### INTERFERING SUBSTANCES

All oxidizing agents which are able to oxidize iodide to iodine are interfering substances. For example, chlorine, chloramines and hypochlorite are interfering compounds. Strong oxidants in general and some reducing agents may cause false positives.

### REFERENCES

<sup>1</sup>L.J. Fischbach. *National Dialysis Standards Reference Book* (1985) 149.

<sup>2</sup>F.P. Greenspan and D.G. Mackellar. *Analytical Chemistry* (1948) 20: 1061.

Manufactured in the USA by: 美国生产商:



**MINNTECH**  
renal systems

Minntech Corporation  
14605 28th Avenue North  
Minneapolis, MN 55447 USA  
Toll Free: 1.800.328.3340



Minntech BV  
Sourthweg 11  
6422PC Heerlen  
The Netherlands  
Tel: +31.455.471.471

EC REP

Minntech Japan Corporation  
4F Shinjuku Yochomachi Bldg.  
10-10 Yochomachi, Shinjuku-ku  
Tokyo 162-0055 Japan  
Tel: +81.03.3225.8680

Minntech Asia Pacific Pte Ltd.  
1A International Business Park  
#05-01 Singapore 609933  
Tel: +65.6227.9698

[www.minntech.com](http://www.minntech.com)

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