

## PERFORMANCE CHARACTERISTICS

The performance characteristics of Rapicide Glutaraldehyde Indicator test strip were established by testing the strips using Rapicide High-Level Disinfectant and Sterilant solution with known concentration of glutaraldehyde under worst case conditions of germicide composition. The test strip exhibited no false positive in solutions containing 1.5% glutaraldehyde when the testing was performed according to the Directions for Use.

## WARNINGS & PRECAUTIONS

- Discard used or expired test strips in a trash receptacle in accordance with federal, state and local laws.
- Keep out of reach of children.
- Do not ingest the strip and/or expose to the eye.
- Do not use Rapicide High-Level Disinfectant and Sterilant solution beyond its recommended use life.
- This device is disposable. DO NOT REUSE.

**THIS PRODUCT IS MOISTURE SENSITIVE AND WILL NOT PERFORM PROPERLY IF STORED INCORRECTLY.** If the container is left open for more than 30 minutes, discard the test strips and use a fresh container.

Chemical test strips such as Rapicide Glutaraldehyde Indicator test strips cannot be relied upon as a means of validating sterilization or disinfection process. Chemical test strips can only establish exposure to specific conditions within the specified performance limits established for the test strip.

## HOW SUPPLIED

Product: Rapicide Glutaraldehyde Indicator Test Strips

Description: Chemical test strips for use in determining whether the minimum recommended concentration of glutaraldehyde is present.

Packaged: 60 strips per bottle, 2 bottles per case

Codes: Reorder Number ML02-0120

All information regarding Rapicide Glutaraldehyde Indicator test strips should be requested from:

Manufactured in the U.K. for:

**MEDIVATORS®**

14605 28th Avenue North  
Minneapolis, MN 55447 U.S.A.  
Toll Free: (800) 444-4729  
Fax: (763) 553-2499

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

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# Rapicide®

## GLUTARALDEHYDE INDICATOR TEST STRIPS

### Instructions for Use

#### INTENDED USE

Rapicide Glutaraldehyde Indicator test strips are glutaraldehyde concentration monitors for use in Rapicide High-Level Disinfectant and Sterilant solution at 35°C (95°F).

#### EXPLANATION OF THE TEST

Rapicide Glutaraldehyde Indicator test strips are semi-quantitative chemical test strips for use in determining whether the concentration of glutaraldehyde, the active ingredient in Rapicide High-Level Disinfectant and Sterilant, is above or below the MRC of 1.5% glutaraldehyde established for this germicide at 35°C (95°F). It is recommended that Rapicide High-Level Disinfectant and Sterilant solution is tested, before each usage, with the Rapicide Glutaraldehyde Indicator test strip in order to guard against dilution, which may lower the glutaraldehyde level of the solution below its MRC.

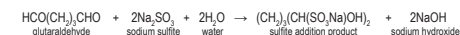
Rapicide Glutaraldehyde Indicator test strips cannot be used to validate the sterilization or disinfection process.

The Rapicide Glutaraldehyde Indicator test strip is used to monitor the glutaraldehyde levels in Rapicide High-Level Disinfectant and Sterilant solution at 35°C (95°F).

#### CHEMICAL PRINCIPLE

Glutaraldehyde reacts with sodium sulfite in the test strip to form a sulfite addition product and an equivalent amount of base (*STEP 1*). If sufficient glutaraldehyde is present, the increase in pH causes a color change in the pH indicator test strip (*STEP 2*).

#### STEP 1



#### STEP 2

NaOH + pH sensitive dye → red color dye

The test strip color is dependent on the glutaraldehyde concentration of the germicide solution, and the time after exposure when the results of the test are read, as described in the *Table 1* below.

**Table 1. Color Development for the Rapiocide Glutaraldehyde Indicator Test Strip**

		Glutaraldehyde Concentration (%)		
Time (seconds)	Unprocessed Indicator Color	<1.5 Fail	1.5 - 1.9 Fail or Pass	> 1.9 Pass
75 seconds	Pale orange / yellow	Yellow, Red/Yellow	Yellow, Red/Yellow, Red	Red

During the first 75 seconds after the test strip has been dipped into the Rapiocide High-Level Disinfectant and Sterilant solution at 35°C (95°F), the pale orange test strip will begin to develop a red color.

At 75 seconds, the strip will exhibit a uniform red color (except for the top 2 mm of the strip) if the concentration of glutaraldehyde is >1.9%. The strip will appear patchy red/yellow or yellow if the solution contains <1.5% glutaraldehyde. In the concentration range of 1.5-1.9% glutaraldehyde, the strip may appear yellow, patchy red/yellow or red. At 75 seconds the color of the strip is stable. A color reading must be taken at this time point for the results to accurately reflect the glutaraldehyde concentration of the Rapiocide High-Level Disinfectant and Sterilant solution.

After 75 seconds the color of the strip regresses toward the original yellow/orange color. The rate of regression is dependent on the glutaraldehyde concentration of the Rapiocide High-Level Disinfectant and Sterilant solution being tested.

## REAGENTS

The indicator pad at the end of the test strip is impregnated with sodium sulfite, dye and buffers.

## STORAGE

Store Rapiocide Glutaraldehyde Indicator test strips in the original bottle with the cap tightly closed. Store at controlled room temperature, 6°C-30°C (43°F-86°F) and in a dry place. Packaging contains an integral desiccant. Return unused strips to container, and ensure lid is properly closed to prevent strip deterioration. Do not store in a refrigerator or freezer.

## SHELF LIFE

The expiration date for the unopened bottle will be stamped on the immediate container label. Do not use this product beyond the expiration date. When opening the bottle for the first time, record the date opened in the space provided on the immediate container label and fill in the 90-day "Do not use after" date directly below.

## PRECAUTIONS:

- Do not use any remaining strips 90 days after opening the bottle.
- Do not freeze.
- Protect strips from exposure to light, heat and moisture.
- Protect strips from exposure to aldehydes, strong acids/alkalis and detergents.
- Packaging contains an integral desiccant. Return unused strips to container, and ensure lid is properly closed to prevent strip deterioration.

## MATERIALS REQUIRED

The following materials are not provided with the Rapiocide Glutaraldehyde Indicator test strips but will be needed for the test:

- Watch or timer
- Paper towel
- Clean polyethylene or polypropylene container to hold the Rapiocide High-Level Disinfectant and Sterilant solution (if required)

## SPECIMEN COLLECTION AND PREPARATION:

Rapiocide Glutaraldehyde Indicator test strips can be used to test Rapiocide High-Level Disinfectant and Sterilant solution at 35°C (95°F) directly in the tray, bucket or other container holding the solution. When this is not feasible, remove approximately 30 ml of the activated Rapiocide High-Level Disinfectant and Sterilant solution from its container and place the solution into a clean plastic container (polyethylene or polypropylene).

## DIRECTIONS FOR USE

1. Ensure that the solution to be tested has been dispensed according to labeling instructions.
2. Dip the indicator pad at the end of the test strip into the container of the Rapiocide High-Level Disinfectant and Sterilant solution at 35°C (95°F) being tested for three seconds and remove. Do not leave the strip in the test solution for longer than three seconds or "stir" the test strip in the solution. Incorrect dipping technique, such as leaving the test strip in the germicide solution longer than the specified 3 seconds and/or swirling the test strip vigorously in the solution, will wash off the reagents in the test strip pad. This can cause a lack of red color formation (FAIL) when testing a solution that will normally test as PASS.

3. Remove excess solution from the test strip pad by touching the long edge of the test strip pad to a paper towel. Do not shake the strip after removal. When removing excess solution, incorrect technique, such as violently shaking the test strip and/or blotting the test strip with the pad face down against a paper towel, can remove the reagents and solution, which can again cause FAIL results for the solutions that will normally test as PASS.

4. Read the results of the color reaction present on the indicator test strip pad at 75 seconds after the test strip is removed from the solution. If read in less than 75 seconds, the color change may be incomplete and may be interpreted incorrectly. Do not read the pad after 75 seconds, as the color will gradually fade making interpretation difficult. The pad will be completely red to indicate an effective concentration of glutaraldehyde in the Rapiocide High-Level Disinfectant and Sterilant solution being tested. Any shade of red is acceptable; the intensity will vary due to concentration variation. If any yellow remains on the test strip pad, the glutaraldehyde concentration of the Rapiocide High-Level Disinfectant and Sterilant solution is below the MRC and should be discarded. Refer to the visual standard on the test strip bottle for interpretation of test results. See interpretation of Test Results for additional important information on the use of this product.

## INTERPRETATION OF TEST RESULTS

When reading the results of the test, the color of the Rapiocide Glutaraldehyde Indicator test strip should be compared to the color chart provided on the test strip bottle. The entire indicator test strip pad, except for the top 2 mm, must be completely red to pass the test indicating that the concentration of active glutaraldehyde is above the MRC. If any yellow remains on the indicator pad apart from the top 2 mm of the strip, the test indicates a failure, verifying that the concentration of glutaraldehyde in the germicide solution is below the MRC and the solution must be discarded. During the reuse life of the Rapiocide High-Level Disinfectant and Sterilant solution, the test must be performed according to the directions for use in order to get consistent, reliable data concerning the concentration of active glutaraldehyde in the solution.

## LIMITATIONS

Although Rapiocide Glutaraldehyde Indicator test strips may give a color reaction with glutaraldehyde and glutaraldehyde-based disinfectants from other manufacturers, their use is limited to Rapiocide High-Level Disinfectant and Sterilant solution at 35°C (95°F). Manufacturers may claim different MRCs for their germicides. Use of the Rapiocide Glutaraldehyde Indicator test strip in a germicide with a different MRC may lead to inaccurate test results.

## QUALITY CONTROL PROCEDURES

### 1. Preparation of Control Solutions

To prepare positive and negative control solutions for testing, obtain a container of unused Rapiocide High-Level Disinfectant and Sterilant solution that has not passed the 28 day expiration mark. Verify that the labelled expiration date for the solution is appropriate. The full strength solution may be used as a positive control. To prepare a negative control, dilute one part of full strength Rapiocide High-Level Disinfectant and Sterilant solution with one part of water at room temperature. Label each control solution appropriately.

### 2. Testing Procedure

Following the directions for use, dip three indicator strips in each of the above freshly prepared solutions. The three strips dipped in the full strength positive control solution should exhibit a complete red color on the indicator pad when read at 75 seconds. The three strips dipped in the diluted negative control should either remain completely yellow or exhibit an incomplete color change to red when read at 75 seconds. Refer to the visual standard on the test strip bottle for interpretation of results.

### 3. Testing Frequency

It is recommended that the testing of positive and negative controls be performed on each newly opened test strip bottle of Rapiocide Glutaraldehyde Indicator test strips. After this initial testing, it is recommended that testing of freshly prepared positive and negative controls be performed on a regular basis as established by your own quality control procedures and program. This testing program will serve to minimize errors between different users, use of outdated materials or product that has been improperly stored or handled.

### 4. Unsatisfactory QC Test performance

If the results obtained from using the positive and negative controls indicate the test strip is not functioning properly, discard the remaining strips. DO NOT USE. For customer support, contact Medivators Reprocessing Systems at 1-800-444-4729.