



PRODUCT BULLETIN

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Date: October 25, 2010

Subject: Medivators Rapicide® Test Strip Accuracy

The accuracy of the new Medivators Rapicide Glutaraldehyde Indicator test strips and their impact on Rapicide disinfectant replacement was recently questioned. A few customers have reported a decreased Rapicide HLD use-life after switching from the 3M Comply, Cold Sterilog™ Chemical Indicator Strips to the new Medivators test strips. As a result, we investigated the situation at two accounts to confirm test strip accuracy and to evaluate the problem cause.

In working with the two customers, we first reviewed the Medivators test strip DFU to ensure proper test strip use which included discussing the differences in DFUs between the Comply and the Medivators strips. In both situations, the customers reported using the Medivators test strips correctly but were still experiencing "premature" Rapicide failure. We then requested a sample of the customer's Rapicide HLD solution and the customer's open vial of test strips for Medivators lab analysis and titrate testing. The customers did not have any Comply strips left, so we used Comply test strips from Medivators R&D supply for testing the Rapicide sample. The customer samples would allow the true Rapicide MRC level to be identified and also confirm if the open test strips were indicating correctly. The Medivators lab analysis and titrate testing revealed:

Customer #1

- 1) The Rapicide HLD glutaraldehyde level was determined to be at 1.7%. This is above the minimum effective use concentration level of 1.5% which means that the Rapicide HLD is a Pass. The Rapicide solution was therefore still effective and could have been used for additional endoscope reprocessing cycles.
- 2) The Medivators brand Rapicide Glutaraldehyde Indicator Test Strips correctly displayed a Pass test result.
- 3) When the Rapicide sample was tested using the Comply test strips, the strip displayed a light yellow/yellow-white coloring which could be interpreted as either a Pass or Fail condition. It is up to the user's subjective interpretation to determine if the Rapicide is good to use, or if it should be discarded and replaced.



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Customer #2

- 1) The Rapiocide HLD glutaraldehyde level was determined to be at 1.5%. This is at the minimum effective use concentration level which means that the Rapiocide must be replaced.
- 2) The Medivators brand Rapiocide Glutaraldehyde Indicator Test Strips correctly displayed a Fail test result.
- 3) When the sample was tested using the Comply test strips, the indicator strip correctly displayed a Fail test result.

Upon review of the samples obtained from these two customers, the Medivators test strips correctly identified the true Pass/Fail condition of the Rapiocide. This confirmed that the test strips are accurately identifying the condition of the Rapiocide. This also identifies that the test strip's Instructions for Use must be closely followed to ensure optimal Rapiocide disinfectant use life.

With Customer #1, whose Rapiocide was still appropriate for further use, incorrect test strip use most likely resulted in the false Fail reading. This highlights the importance of correctly following the DFUs. Customers should be reminded that:

- The test strip must be dipped in the Rapiocide for 3 seconds. If the test strip is only dipped for 1 or 2 seconds, it would not have enough disinfectant on it for an effective Pass/Fail identification.
- The strip should not be shaken or blotted – excess solution should be removed by touching the long edge of the strip to a paper towel.
- The strip should be read at precisely 75 seconds – always use the timer.
- The test strips must always be kept sealed in the supplied test strip vial container, and only take out what will be used to test the Rapiocide HLD at that moment.
- The test strips should not be cut in half in an attempt to obtain more uses from them as cutting the test strips will affect their chemical composition and result in false readings.

With Customer #2, the Rapiocide was at 1.5% MRC so it definitely required replacement which was accurately identified by the Medivators test strips. Upon discussing the R&D results with the customer, they had noticed a decreased number of reprocessing cycles since they switched from the Comply strips. This decrease could be due to specific test strip differences including:

- As the Comply test strips move beyond the 5 – 8 minute read window, they continue to change until a Pass state is ultimately reached, which would then indicate a false Pass. If the Rapiocide MRC is marginal or failed (<1.5% glutaraldehyde) and the test strip is read beyond the eight minute mark, a Fail test result could appear as a Pass.
- When the Comply test strip reading is in the marginal Pass/Fail area of the Rapiocide M.R.C. Comparison Chart, the color reading is very subjective and open to customer interpretation which could be identified as a Pass, when it truly is a Fail.
- As the new Medivators Rapiocide test strips move beyond the 75 second read time, they continue to change to a Fail state which could represent a false negative. If the Rapiocide MRC is passing (>1.5% glutaraldehyde) and the test strip is read beyond the 75 second mark, a true Pass result can appear as a Fail.



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As this testing has confirmed, customer familiarity with the correct use of the strips is extremely important to obtaining accurate test strip results and to ensuring optimal Rapicide use life. While not related to the test strip question, an effective manual cleaning process of brushing and flushing is critical to reducing an endoscope's bioburden and bacterial load. Using Intercept detergent and Scope Buddy help to effectively reduce the bacterial burden which decreases the load on Rapicide. A decreased load helps to extend Rapicide's use life.

A copy of this product bulletin is available on the Medivators website located at www.minntech.com/medivators by selecting "Medivators Reprocessing Systems" followed by "Resource Center." If you have any questions regarding this Product Bulletin, please contact Medivators Technical Support at 1-800-444-4729.