

Product Bulletin

For Distribution To:

- International Distributors
- International Management
- U.S. Field Sales & Clinical Specialists
- U.S. Technical & Field Service

Date: November 19, 2015

RE: RAPICIDE® PA Test Strips Stability

Medivators has received several customer inquiries regarding the stability of the RAPICIDE PA Test Strips over extended periods of time at elevated temperatures.

RAPICIDE PA Test Strips are used to ensure that RAPICIDE® PA High-Level Disinfectant is above the minimum recommended concentration (MRC) of 850ppm following an endoscope reprocessing cycle. The strips have been evaluated for efficacy by both the manufacturer and by Medivators.

Medivators has recently performed an extended elevated temperature stability study with RAPICIDE PA Test Strips. The study tested the efficacy of the strips when stored at 60°C (140°F) over a three-week period. Weekly analysis was done to ensure that efficacy of the RAPICIDE PA Test Strips was being maintained. Upon conclusion of the three-week period, it was determined that all tests passes and RAPICIDE PA Test Strips, as packaged, can be said to be stable at 60°C (140°F) for a period of at least three weeks.

Based on this, the validity of the Quality Control testing reported on the Certificate of Analysis for each lot of test strips will remain in effect during shipping of the product from Medivators to a facility or between facilities. A facility may choose to perform their own Quality Control test or they can rely on the Medivators supplied Certificate of Analysis.

Instructions for both options can be found in the directions for use included with the product or online at www.medivators.com.

If you have any questions regarding this Product Bulletin please contact the Medivators Customer Support group at 1- 800-444-4729.

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