

Product Bulletin

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Date: April 7, 2015

RE: Efficacy of RAPICIDE® High-Level Disinfectant, RAPICIDE® PA and RAPICIDE® OPA/28 against Carbapenem-resistant *Enterobacteriaceae* (CRE)

Summary: This study measured the rate-of-kill of CRE inoculated into the RAPICIDE High-Level Disinfectant (HLD) family. After various exposure times (1, 3 and 5 minutes), the number of survivors was determined. At all exposure times, no survivors were recovered. The germicides have effected a >99.9999% or >6.04-log reduction in the number of CRE in 1 minute at label claim parameters (Accuratus Lab Services Reports A18139, A18140 and A18141).

Introduction: Carbapenem-resistant *Enterobacteriaceae* are gram-negative bacteria with resistance to nearly the entire carbapenem class of antibiotics. *Klebsiella* species and *Escherichia coli* are examples of *Enterobacteriaceae*, a normal part of the human gut bacteria that can become carbapenem-resistant. They contain enzymes that break down carbapenems and make them ineffective. Healthy people usually do not acquire the CRE infection; patients in hospitals, nursing homes and other healthcare settings have the highest risk, especially those on long courses of antibiotic treatment. The CRE bacteria resistant to carbapenems are very difficult to treat and can be deadly. Germicides' mechanisms for kill are different than antibiotics and are not compromised by the CRE plasmid acquisition by the gram-negative bacteria. The time kill chart shows that the MEDIVATORS family of HLDs performs effectively and makes no difference whether the *E. coli* has the CRE adaptation or not.

The present study was designed to evaluate MEDIVATORS® RAPICIDE products for their ability to kill CRE under the label claims for each product as a high level disinfection. Three studies contain results based on time kill of 1, 3 and 5 minutes (Chart 1), while three additional studies show label claims confirming the HLD achieved with added organic load (Chart 2).

Methods: The organism was grown to a high cell density in a rich organic medium. Before testing, 5% serum was added to the cell suspension as an organic soil. The presence of the organic soil helps to evaluate the ability of the germicide to be effective on devices that have been cleaned but still have a low residual level of body fluids. Aliquots of RAPICIDE High-Level Disinfectant, RAPICIDE PA AND RAPICIDE OPA/28 were warmed to 35°C, 30°C and 20°C respectively, and then cell suspensions were added. At exposure times of 1, 3 and 5 minutes an aliquot of germicide/cell mix was removed and added to a neutralizer to stop the action of the germicide. The number of survivors at each exposure time was quantified by filtering the neutralizer and culturing the filter on agar medium. The number of cells present in the germicide at time zero (test population control) was determined and the efficacy of the neutralizer was confirmed.

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Medivators Inc.
14605 28th Avenue North
Minneapolis, MN
55447-4822 USA
Tel: +1.800.444.4729
Fax: +763.553.3387

Medivators BV
Sourthweg 11
6422PC Heerlen
The Netherlands
Tel: +31.45.5.471.471
Fax: +31.45.5.429.695

Cantel Medical Asia/Pacific Pte. Ltd.
1 A International Business Park
#05-01 Singapore 609933
Tel: +65.6227.9698
Fax: +65.6225.6848

Medivators Inc. Beijing Representative Office
Room 1801, Floor 18th, Tower A,
Beijing Marriott Hotel, Office Building
No. 7, Jianguomen South Avenue,
Dongcheng District, Beijing 100005 China
Tel: +86 10 65204039

www.medivators.com

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Results: As shown in the table, there were no survivors at any of the exposure times. These data indicate that RAPICIDE® High-Level Disinfectant, RAPICIDE® PA AND RAPICIDE® OPA/28 have the ability to kill CRE (at a cell population considerably higher than what would be expected on or in medical devices) under the test conditions used in this study.

Rate-of-kill test of RAPICIDE High-Level Disinfectant, RAPICIDE PA AND RAPICIDE OPA/28 against CRE (A18143, A18144 and A18142)

CHART 1

Exposure time (minutes)	Number of survivors (CFU/ml)	Log reduction Rapicide	Number of survivors (CFU/ml)	Log reduction Rapicide PA	Number of survivors (CFU/ml)	Log reduction Rapicide OPA/28
1	<1	>6.04	<1	>6.09	<1	>6.28
3	<1	>6.04	<1	>6.09	<1	>6.28
5	<1	>6.04	<1	>6.09	<1	>6.28

Results of HLDs used according to label claim on CRE as a carrier test

CHART 2

Exposure time (minutes)	Accuratus Report: A18140	Log reduction Rapicide	Accuratus Report: A18141	Log reduction Rapicide PA	Accuratus Report: A18139	Log reduction Rapicide OPA/28
5	3-31-15	>6.47	3-31-15	>6.16	3-31-15	>6.27