Efficacy against New and Emerging Pathogens

Introduction:

Tests for disinfection and sterilization of reusable medical devices are highly standardized to enable consistency from facility to facility. With the emergence of new pathogens, or new strains of pathogens, there is typically a lag between the discovery of the pathogen and the establishment of an effective and standardized disinfection test to kill it.

Like other High-Level Disinfectants/Liquid Chemical Sterilants (HLD/LCS), ACECIDE-C has been tested for efficacy against a wide variety of pathogens including two types of bacterial spores, mycobacterium, enveloped and non-enveloped viruses, and both gram positive and gram-negative bacterium. These tests encompass a wide variety of highly resistant organisms. In addition, testing protocols for HLD/LCS have many built-in safety factors. This ensures that the HLD/LCS process will remain effective despite possible variations in the resistance of microorganisms.

One common healthcare-associated infectious microorganism is discussed below.

*Clostridium difficile*

*Clostridium difficile* is a spore forming bacterium that has become an increasingly dangerous healthcare-associated pathogen. During efficacy testing, safer “surrogate” or substitute organisms are used to replicate the resistance of dangerous pathogens. When testing effectiveness of High Level Disinfectants/Liquid Chemical Sterilants the surrogate organism used is *Clostridium sporogenes*. Efficacy testing of chemical disinfectants against *Clostridium sporogenes* is performed using the AOAC sporicidal method. This method is very strenuous and difficult to pass due to Clostridium spores being incorporated into a dried matrix of bioburden.

Testing of ACECIDE-C against a spore suspension of *Clostridium sporogenes* showed a 6-log reduction of spores in under two minutes. When the endoscope is reprocessed within the OER-Pro with ACECIDE-C, a 7-minute contact time provides a safety factor of 5 minutes. With the proven effectiveness of ACECIDE-C against both free and bound spores in addition to the robust safety factor, it is reasonable to conclude that *Clostridium difficile* bacteria and *Clostridium difficile* spores that may remain on an endoscope after clinical use would be destroyed when reprocessed according to Olympus endoscope, OER-Pro, and ACECIDE-C instructions for use.

Cindi Linville  
Director of Quality  
Best Sanitizers, Inc  
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