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Disinfection Efficacy Validation for Architectural Finishes – Preliminary Study Results

Introduction

This article reviews the study "Disinfectant Efficacy Validation Summary Report for National Institutes of Health's (NIH) Aseptic Processing Facilities (APF)," which was developed by the Division of Technical Resources/Facilities Compliance and Inspection Section (DTR/FCIS) in cooperation with the Office of Research Support and Compliance (ORSC) and the Clinical Center Department of Laboratory Medicine (DLM) and executed under contract by Boston Analytical. This report was based on the execution of "PRO-0968-BA Disinfectant Efficacy Surface Coupon Evaluation for National Institute of Health (NIH)." The study was principally intended to validate the use of various cleaning materials and processes for cleanroom surfaces, but this article explores how that same data can be leveraged to improve the selection of materials of construction for use in cleanrooms based on cleaning efficacy.

Scope and Rationale

The study design was based on United States Pharmacopeia (USP) Chapter <1072>, "Disinfectants and Antiseptics," and AOAC Chapter 960.09, "Methodology for Surface Disinfectant Efficacy Testing." DTR/FCIS was responsible for analyzing the architectural finishes installed throughout the Aseptic Processing Facility (APF) cleanroom portfolio as well as designing the coupon requirements to represent the most typical architectural finishes and mounting specifications to ensure they would be testable. The coupons represented epoxy-coated gypsum board, manufactured panels (smooth finish uPVC and Fiberglass-reinforced plastic with gel coat finish), welded sheet vinyl, epoxy resin flooring, cleanroom acoustical ceiling tile, 304 stainless steel, and glass. DLM was responsible for identifying microorganisms of concern from environmental monitoring of the NIH cleanroom portfolio, including spore forming and non-spore forming bacteria, yeasts, and molds. DLM provided isolates of the 20 identified challenge microorganisms derived from species collected in the cleanrooms. ORSC provided the disinfectant protocols for the use of specific products identified by the APF cleaning protocol, which is executed by contractors under ORSC's control. The disinfectants included Vesphene® III, LpH® III, and Peridox RTU®.

Testing

All coupons were cleaned and prepared following a protocol developed between NIH and Boston Analytical. All isolates were prepared using methodologies approved by NIH. Each surface coupon was inoculated with 200 µL of the microbial suspension in a drop-wise fashion. The inoculated coupon was allowed to dry in a biosafety cabinet (BSC) and then sprayed with the appropriate disinfectant. The coupon was saturated with the disinfectant for the required contact time. After the required contact time, the coupons were inverted over a deep petri dish and rinsed with 20 mL of sterile buffer solution. The resulting test solution was then used to prepare subsequent plating. The test samples and positive and negative controls were inverted (i.e., media side up) and incubated per the approved protocol. Post-incubation, the samples were assayed, including positive and negative controls, and colony purity was determined (a pure colony is defined as macroscopically uniform and consistent with that of the intended challenge microorganisms).

Results

Table 1: Cleaning Efficacy Study Summary, below, provides a simplified summary of the study's results. The results are color-coded to indicate whether the required Log10 reduction in viable microorganisms was met. Green indicates that the criteria was consistently met by all three disinfectants against that microorganism on that coupon (e.g., architectural finish); Yellow indicates that some of the disinfectants demonstrated efficacy (typically always included Peridox RTU®); and Red indicates that none of the disinfectants demonstrated efficacy against the combination of that microorganism and coupon type.

Conclusions

There are multiple ways to interpret the findings of this study. Routine environmental monitoring is performed across the APF portfolio. The vertical axis then lists various isolates; detection of isolates of special concern (as in columns #4, 10, or 18-20) indicate that the cleaning SOP should be modified to prompt re-cleaning with a product that has a higher demonstrated efficacy, including Peridox RTU®. The horizontal axis shows various materials. Certain rows (including epoxy resin flooring, cleanroom acoustical ceiling tiles and epoxy-coated gypsum board) performed poorly. Micrographs of these materials show an unavoidable degree of surface texture which may provide harborage and protection for microorganisms from adequate exposure to the disinfectants, as applied. This suggests that the use of such materials in cleanrooms requires very careful consideration.

While Peridox RTU® is highly effective at achieving the required Log kill of these microorganisms, it contains peracetic acid, which is particularly aggressive towards certain long-chain polymers. It has been associated with the accelerated failure of certain architectural finishes, particularly epoxy-coated drywall. Extra care is necessary when specifying and detailing such materials, and preference should be given to those which function to better support the efficacy of disinfectants, where possible.

Additional Reading

1. NIH Design Requirements Manual, CH-13

Table 1: Cleaning Efficacy Study Summary

Surface	Micrococcus luteus (Facility Isolate 1)	Staphylococcus hominis (Facility Isolate 2)	Kocuria flava (Facility Isolate 3)	Bacillus megaterium (Facility Isolate 4)	Janibacter spp. (Facility Isolate 5)	Mycolicibacterium mucogenicum (Facility Isolate 6)	Rhodococcus spp. (Facility Isolate 7)	Streptomyces spp. (Facility Isolate 8)	Corynebacterium jeikeium (Facility Isolate 9)	Paenibacillus species (Facility Isolate 10)	Rosemonas mucosa (Facility Isolate 11)	Sphingomonas paucimobilis (Facility Isolate 12)	Pantoea septica (Facility Isolate 13)	Moraxella species (Facility Isolate 14)	Filobasidiella neoformans (Cryptococcus neoformans) (Facility Isolate 15)	Candida parapsilosis (Facility Isolate 16)	Phaeoannellomyces elegans (Facility Isolate 17)	Aspergillus fumigatus (Facility Isolate 18)	Cladosporium spp. (Facility Isolate 19)	Talaromyces spp. (Facility Isolate 20)
(Acrovyn – Pebbly Finish)																				
(Acroplast – Smooth Finish)																				
Polymer Panel																				
Welded Sheet Vinyl																				
304 Stainless Steel																				
Glass																				
Epoxy Resin																				
Clean Room Acoustic Ceiling Tiles																				
Epoxy Coated Gypsum Board																				
	ALL PASS	**ALL PASS**	**ALL PASS**	**All fail except** - Peridox RTU® / 5 Minutes	**FAIL** - Vesphene® III / 10 Minutes	**ALL PASS**	**ALL PASS**	**All pass except** - Vesphene® III / 10 Minutes	**ALL PASS**	**All fail except** - Peridox RTU® / 5 Minutes	**All pass except** - Vesphene® III / 10 Minutes	**ALL PASS**	**ALL PASS**	**ALL PASS**	**ALL PASS**	**ALL PASS**	**ALL PASS**	**All fail except** - Peridox RTU® / 5 Minutes	**All fail except** - Peridox RTU® / 5 Minutes	**All fail except** - Peridox RTU® / 5 Minutes

(GREEN) Criteria was met by all disinfectants

(YELLOW) Criteria was met by some disinfectants

(RED) Criteria was met by none of the disinfectants