VALIDATION OF PROEDGE DENTAL WATER LABS NEUTRALIZATION METHOD EFFECTIVENESS OF PATTERSON TABLETS

Development:

Dental unit water samples utilizing continuous treatment water line maintenance products contain residual antimicrobial agents. The residual antimicrobial agents must be effectively neutralized to ensure that there is no inhibitory effect on microorganism when conducting heterotrophic plate counts.

Procedure summary:

The products tested are indicated in the following table:

Product Name	Active Ingredient(s)
Patterson Tablets	Silver

The following organisms were tested against each product and were chosen based upon ISO/FDIS 16954 (Dentistry – Test Method for Dental Unit Waterline Biofilm Treatment)

Organism	MRI Code	ATCC Number
Klebsiella pneumoniae	KL7	700603
Pseudomonas aeruginosa	Ps2	27853

Neutralization effectiveness testing was performed according to SOP L-268 which was written to comply with ASTM 1054 "Standard Test Methods for Evaluation of Inactivators of Antimicrobial Agents."

The following tests were performed in triplicate for each organism/product combination:

A. Neutralization Effectiveness:
0.1 mL of product was neutralized and spread over ½ of a plate. The same was repeated on the other ½ of the plate. The product was allowed to dry and then 0.1 mL of a $5x10^2$ cfu/mL (50 cfu/mL) suspension of the organism was plated in duplicate onto the plate such that the organism was not inoculated outside the margin of the dried product.

C. Viability/Toxicity:
0.1 mL of a $5x10^2$ cfu/mL suspension of the organism was plated in a similar manner to Test A.

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D. Material Control:
0.1 mL of non-neutralized product was plated as in Test A. 0.1 mL of a $5x10^2$ cfu/mL suspension of the organism was also plated in a similar manner to Test A.

All plates were incubated aerobically overnight at 36±2°C. After incubation, colonies were enumerated and duplicate counts averaged.

For each product/organism combination, Test A and Test D were compared to Test C using a Student's *t*-test. Neutralization was considered effective if the Test A recovery population was not significantly different from the Test C organism viability population (i.e., p-value was >0.05). The product was considered effective against the organism if the Test D recovery population was significantly smaller than the Test C organism viability population (i.e., p-value was ≤0.05).

Results summary:

Results for each replicate of each organism are presented in Table 1. Results statistically show that the neutralization method is effective. Patterson Tablets active ingredient was effectively neutralized.

Table 1. Summary of Neutralization Effectiveness Testing

		p-Value		Effective (Y/N)	
Product	Organism	Test A vs Test C	Test D vs Test C	Neutralization (p-value >0.05)	Product (p-value ≤0.05)
Patterson	*P. aeruginosa*	0.91	0.60	Y	N
Patterson	*K. pneumoniae*	0.59	0.34	Y	N

Conclusion:

The results of this validation are acceptable, and the ProEdge Neutralization Method is effective for the neutralization of Patterson Tablets.