

Antimicrobial Efficacy of Two Hydrogen Peroxide Lens Care Products Against Bacteria, Yeast, Mold and *Acanthamoeba* with Rigid Gas Permeable Lenses

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Introduction

Rigid Gas permeable (RGP) contact lenses, in the form of scleral and corneal lenses, are used in orthokeratology (ortho-k) for the correction of myopia, refractive disorders, and slowing the progression of myopia.

Clear Care® and Clear Care with HydraGlyde (Clear Care Plus®) are 3.0% hydrogen peroxide lens care solutions indicated for cleaning and disinfecting RGP contact lenses. Clear Care Plus® is a preservative-free, phosphate buffered, 3.0% hydrogen peroxide solution with advanced wetting properties. Similar to the original Clear Care formulation, Clear Care Plus® contains Pluronic 17R4 as a surfactant and advanced wetting agent.

Purpose

To evaluate the antimicrobial efficacy of hydrogen peroxide solutions, against bacteria, yeast, mold, and two strains of *Acanthamoeba*, for cleaning and disinfecting silicone acrylate and fluorosilicone acrylate RGP lenses. Additionally, the effectiveness of regimen instructions in cleaning and disinfecting RGP lenses was evaluated.

Materials & Methods

Clear Care® and Clear Care Plus® were evaluated in this study. Hydrogen peroxide systems require a contact lens case containing a platinum disc (AOCup) that neutralizes the hydrogen peroxide over the course of the disinfection time. RGP lenses evaluated were silicone acrylate, Boston II (itafocon A), and a fluorosilicone acrylate, Boston XO (hexafocon A).

1. ISO 14729 Stand-alone test:
Solutions were inoculated with 10⁵-10⁶CFU/mL of bacteria, yeast, or mold (with and without organic soil).

- *Staphylococcus aureus* ATCC 6538
- *Pseudomonas aeruginosa* ATCC 9027
- *Serratia marcescens* ATCC 13880
- *Candida albicans* ATCC 10231
- *Fusarium keratoplasticum* ATCC 36031

2. *Acanthamoeba* testing:
A modified version of ISO 14729 was used to evaluate solution efficacy in the presence of RGP lenses. Lenses were inoculated with two strains of *Acanthamoeba* trophozoites and cysts.

- *A. castellanii* ATCC 50370
- *A. polyphaga* ATCC 30461

Inoculum controls were prepared at the beginning of the study. All samples were evaluated for viability loss at the recommended disinfection time (6 hours). For *Acanthamoeba* testing, inoculum controls and surviving organisms were determined using 50% endpoint. Average log reductions were determined from replicate samples (n≥3). Contact lenses and solutions were assessed for CFU/lens and corresponding solution.

References

1. Crary MW, R; McAnally, C; Gabriel, M; Shannon, P. Differential Antimicrobial Efficacy of MultiPurpose Solutions Against *Acanthamoeba* spp Trophozoites. *Optom Vis Sci* 2018;82(E-abstract 185366).
2. Gabriel MM, Cindy McAnally, John Bartel, Rhonda Walters, Linda Clark, Monica Crary, and Stephen Shannon. Biocidal Efficacy of a Hydrogen Peroxide Lens Care Solution Incorporating a Novel Wetting Agent. *Eye and Contact Lens* 2019;45(3):164-170.
3. US Food and Drug Administration. Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products. US Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD, May 1, 1997.
4. ISO 14729:2001/A1:2010. Ophthalmic Optics - Contact Lens Care Products - Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses.

Results

ISO Organisms: Regimen Test

- Regimen test criteria: For each microbial species, the average regimen recovery count (for all lots tested) shall be no more than 10 cfu for each lens type/storage solution combination.
- Conclusion: For all ISO microorganisms tested, an average of <10 CFU/lens-solution combination was recovered for both RGP contact lens types for both solutions (Table 1).

Lens Material	Microorganism	Initial CFU / Lens for Clear Care Plus®	CFU/ Lens and Soaking Solution after 6 Hours (n=12)	Initial CFU / Lens for Clear Care®	CFU/ Lens and Soaking Solution after 6 Hours (n=12)
Silicone acrylate	<i>S. aureus</i>	1.0 x 10 ⁶	<1	6.3 x 10 ⁵	<1
	<i>P. aeruginosa</i>	7.4 x 10 ⁵	0	6.7 x 10 ⁵	0
	<i>S. marcescens</i>	6.3 x 10 ⁵	<1	7.1 x 10 ⁵	0
	<i>C. albicans</i>	5.0 x 10 ⁵	0	5.1 x 10 ⁵	0
	<i>F. keratoplasticum</i>	4.1 x 10 ⁵	0	4.1 x 10 ⁵	<1
Fluorosilicone acrylate	<i>S. aureus</i>	1.4 x 10 ⁶	0	6.8 x 10 ⁵	0
	<i>P. aeruginosa</i>	8.4 x 10 ⁵	0	7.0 x 10 ⁵	<1
	<i>S. marcescens</i>	5.7 x 10 ⁵	0	5.3 x 10 ⁵	0
	<i>C. albicans</i>	5.6 x 10 ⁵	0	3.7 x 10 ⁵	0
	<i>F. keratoplasticum</i>	4.1 x 10 ⁵	<1	6.3 x 10 ⁵	<1

Table 1. Regimen Disinfection Efficacy of Clear Care and Clear Care Plus against Bacteria, Yeast and Mold
Data reflect mean average CFU/lens from 4 lenses and 3 lots of product.

Acanthamoeba: Antimicrobial Efficacy in the Presence of RGP lens

- There are currently no criteria for biocidal testing against *Acanthamoeba*. Figure 3 shows the following results:
 - The log reduction against trophozoites of the two *Acanthamoeba* strains for both solutions ranged from 5.5-6.2 logs.
 - The log reduction against cysts of the two *Acanthamoeba* strains for both solutions ranged from 1.9-2.6.

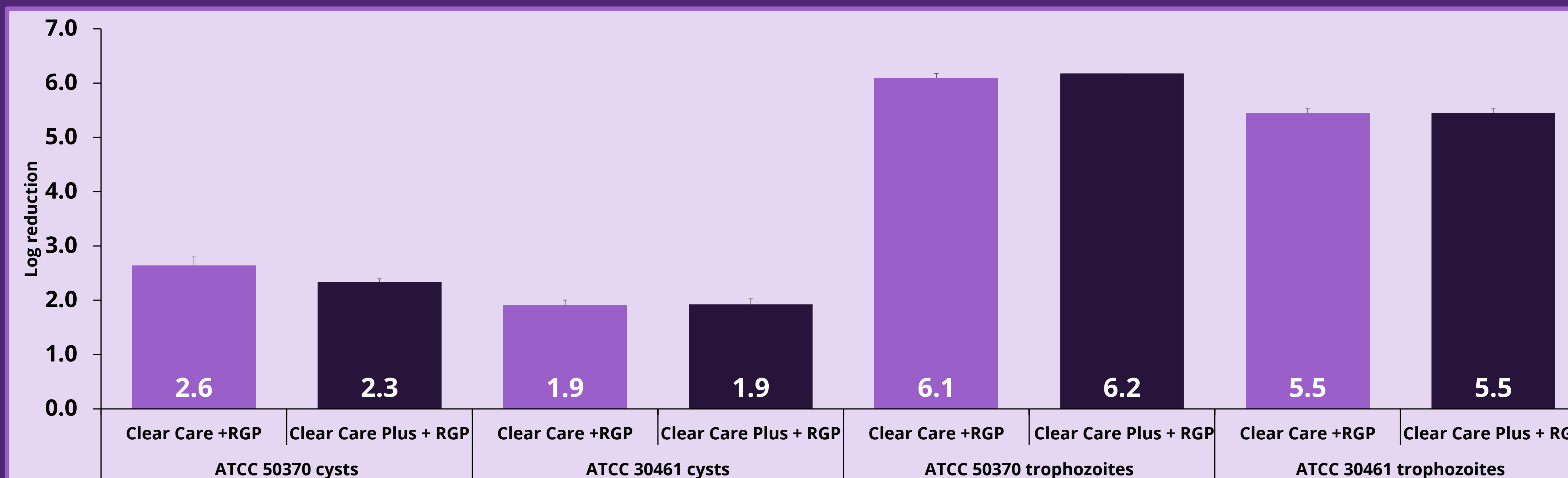


Figure 3. Antimicrobial Efficacy of Clear Care® and Clear Care Plus® Against *Acanthamoeba* in the presence of RGP lenses

Conclusions

- Clear Care® and Clear Care Plus® exceed ISO lens care solution disinfection efficacy requirements for the Stand-alone and Regimen test (without a rub step), and has been shown to be effective against *Acanthamoeba* trophozoites and cysts.
- Clear Care® and Clear Care Plus® 3.0% hydrogen peroxide solutions are effective in disinfecting RGP contact lenses.

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ISO Organisms: Stand-Alone Antimicrobial Efficacy

- Stand-alone primary test criteria require an average log reduction of ≥3.0 logs (99.9%) for bacteria and ≥1.0 log (90.0%) for yeast and mold at the recommended DT with no increase at 24 hours.
- The two hydrogen peroxide solutions exceeded the ISO 14729 primary criteria for log reduction of microorganisms at the 6-hour DT. There was no increase in mold or yeast at 24 hours. Figures 1 and 2 show the following results
 - The log reduction for bacteria (*S. aureus*, *P. aeruginosa*, and *S. marcescens*) was between 4.4-5.1 logs with or without organic soil.
 - The log reduction for yeast (*C. albicans*) was 4.4-4.9 logs with or without organic soil.
 - The log reduction for mold (*F. keratoplasticum*) was 2.9-3.5 logs with or without organic soil.

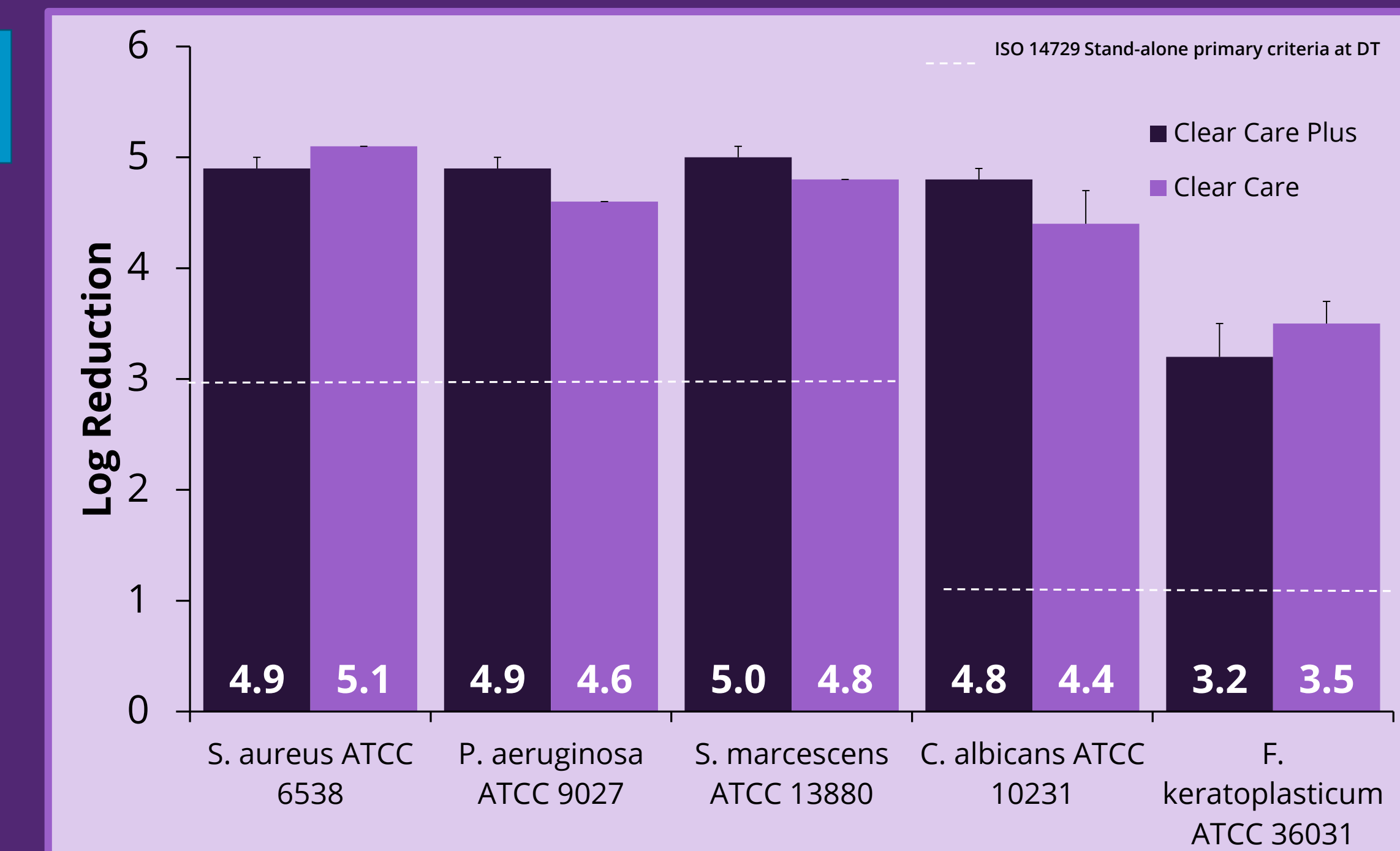


Figure 1. Antimicrobial Efficacy of Clear Care® and Clear Care Plus® Against Bacteria, Yeasts and Mold with organic soil
Data reflect mean ± SD; n=3. Dashed line represents acceptance criteria.

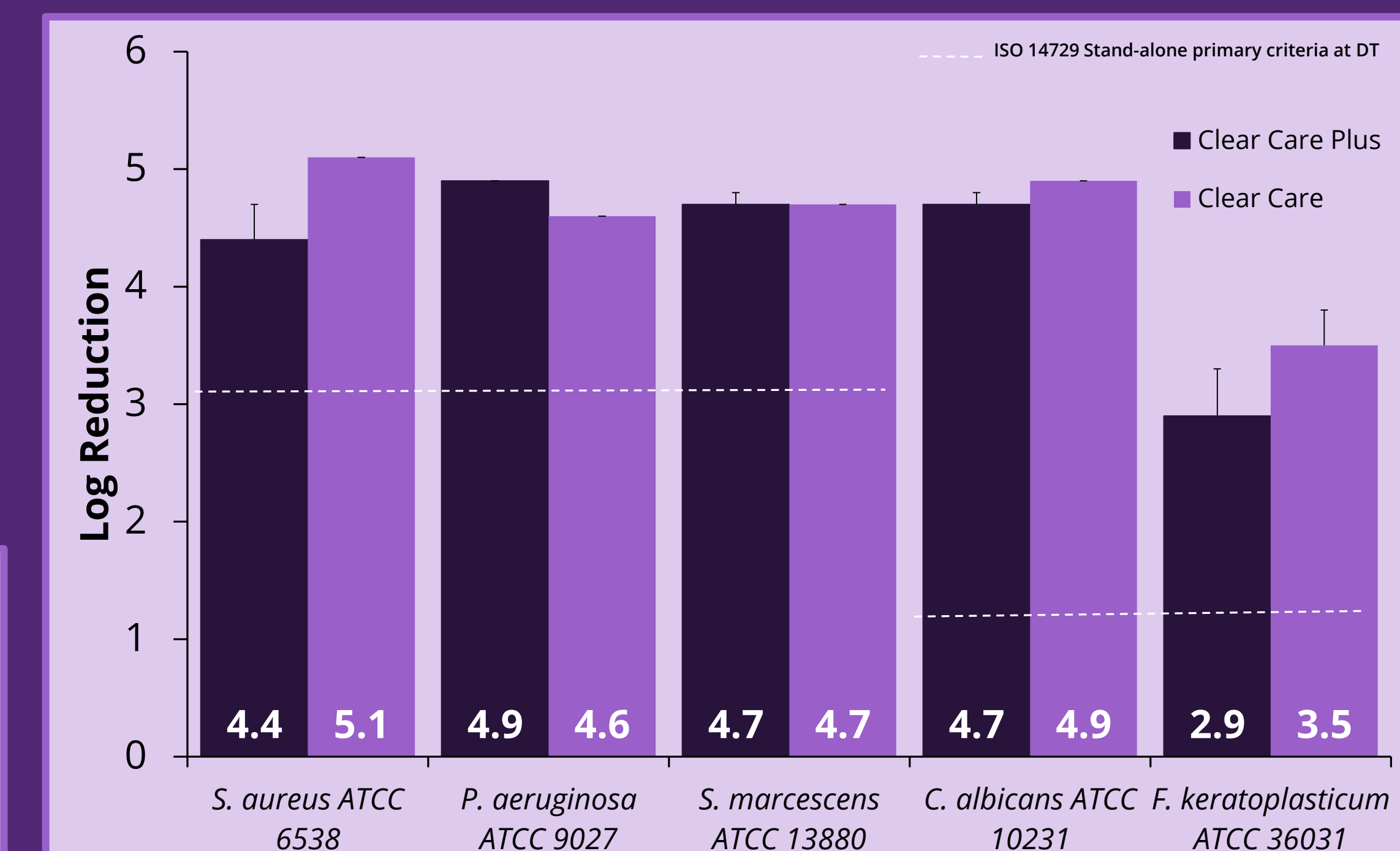


Figure 2. Antimicrobial Efficacy of Clear Care® and Clear Care Plus® Against Bacteria, Yeasts and Molds without organic soil
Data reflect mean ± SD; n=3. Dashed line represents acceptance criteria