

Tested for some of
the most extreme
environments
in the world.

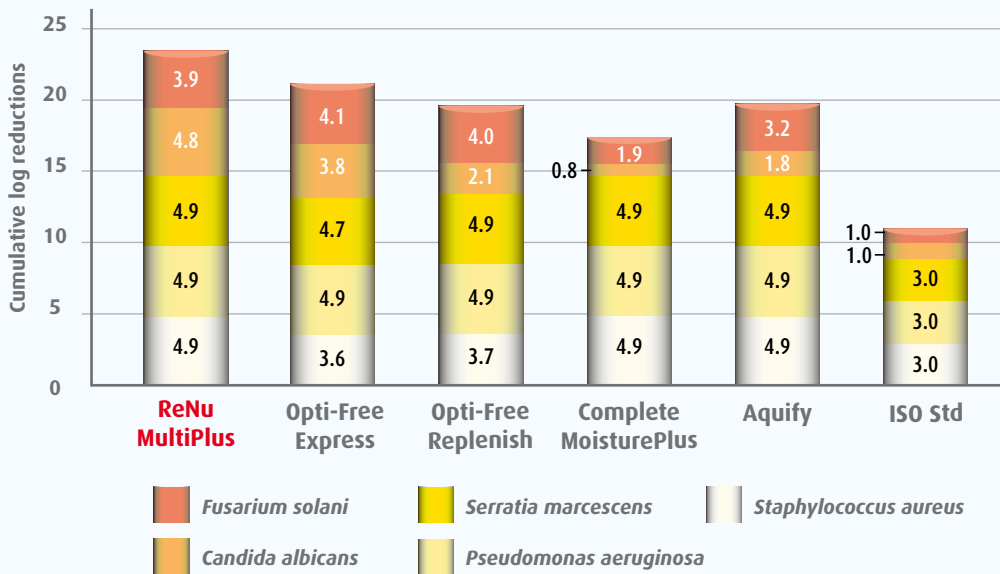


Bausch & Lomb
ReNu
MultiPlus®
Multi-Purpose Solution

that fresh lens feeling every day.

Exceeds international standards.

ISO/FDA STAND-ALONE PROCEDURE FOR DISINFECTING PRODUCTS*

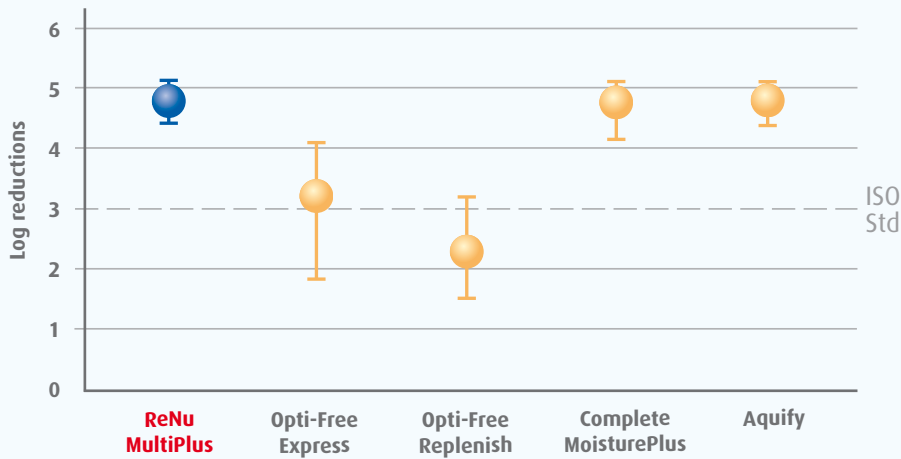


ReNu MultiPlus® Solution offers exceptional disinfection efficacy against a broad range of ocular pathogens.¹

* Results of in vitro study following FDA/ISO stand-alone procedure for disinfecting products. Log reduction values at a minimum soak time without organic soil. Primary criteria for effective disinfection are defined as a reduction in the number of bacteria by a minimum of 3 log (99.9%) and a reduction of mould and yeast by a minimum of 1 log (90%) within the recommended disinfection time. Graph depicts mean log reduction measured after manufacturer's recommended disinfecting time (soak only).

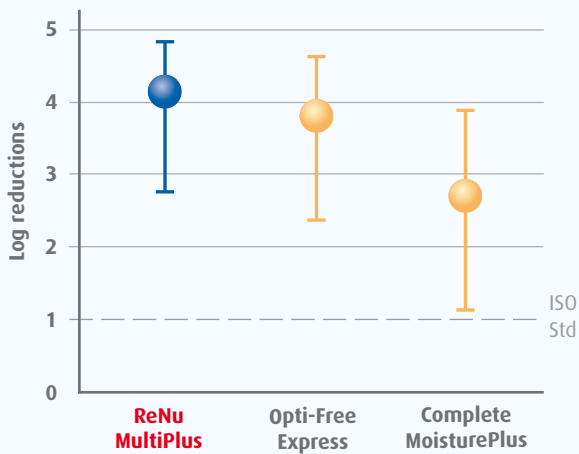
Effective against a broad spectrum of real-world microorganisms.

DISINFECTION EFFICACY AGAINST CLINICAL ISOLATES OF *Staphylococcus aureus**



ReNu MultiPlus® Solution surpasses the ISO/FDA 3 log reduction threshold for all 11 clinical isolates tested, offering exceptional disinfection.¹

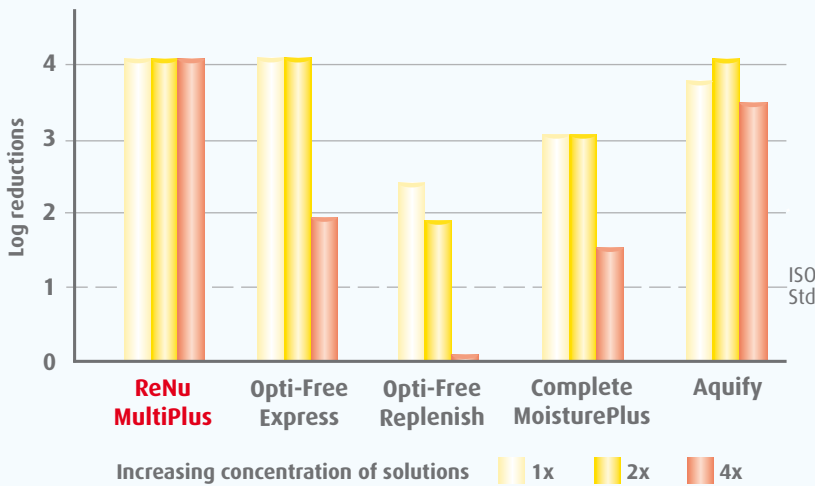
DISINFECTION EFFICACY AGAINST CLINICAL ISOLATES OF *Fusarium solani**



ReNu MultiPlus Solution surpassed the ISO/FDA 1 log reduction threshold for all 20 clinical isolates tested, offering exceptional disinfection.¹

Exceptional efficacy in non-compliant conditions.

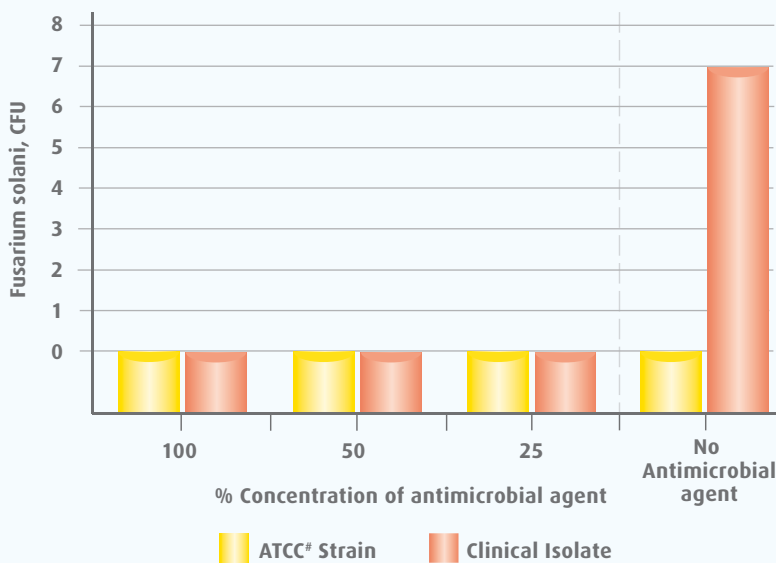
DISINFECTION EFFICACY AGAINST *Fusarium solani* UNDER SOLUTION EVAPORATION CONDITIONS†



Efficacy of ReNu MultiPlus® when used under extreme conditions simulating the user's contact lens case or bottle of product being left open and 1/2 or 3/4 of the water being removed by evaporation.

ReNu MultiPlus Solution continually surpasses the ISO/FDA 1 log reduction threshold and retains exceptional disinfection at increased concentrations against clinical isolates of *Fusarium solani*.²

VIABLE FILM-PROTECTED *Fusarium solani* REMAINING UNDER SOLUTION REUSE CONDITIONS§



Efficacy of ReNu MultiPlus when used under extreme evaporative conditions simulating the user's contact lens case being left open, producing film-protected microorganisms.

ReNu MultiPlus Solution retains superior disinfection efficacy against film-protected *Fusarium solani* at all concentrations of antimicrobial agent.²

† Results of in vitro study to evaluate the ability of solutions formulated at 2X and 4X, including disinfectant, to disinfect *F. solani* compared to normal (1X) solution. Procedure performed following FDA/ISO stand-alone procedure for disinfecting products. Primary criteria for effective disinfection are defined as a reduction in the number of mould and yeast by a minimum of 1 log (90%) within the recommended disinfection time. Graph depicts mean log reduction measured after manufacturer's recommended disinfecting time (soak only).

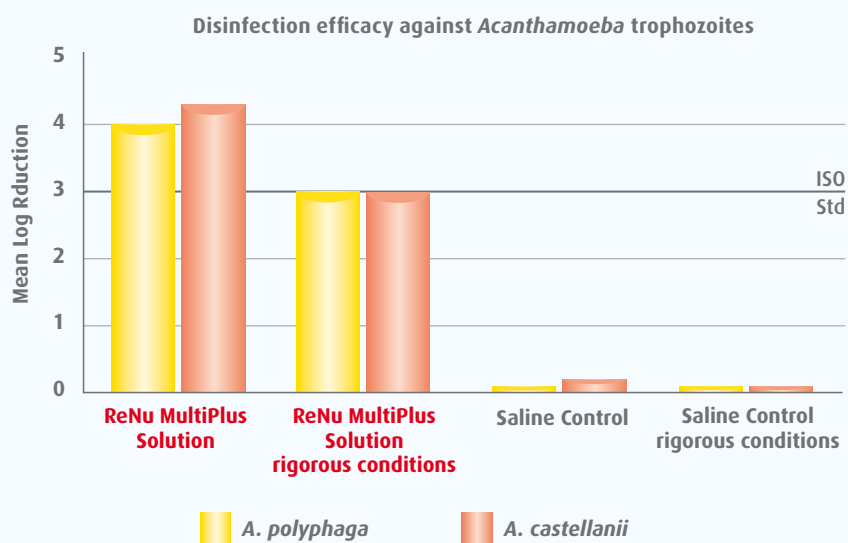
§ An in vitro study evaluated the ability of solutions to disinfect film-protected *F. solani* isolates. Each *F. solani* isolate was added to disinfecting-free solution and allowed to dry (film production). Film was then challenged with fresh solution containing various levels of the appropriate disinfectant (MultiPlus; PHMB) for a standard 4-hour disinfection cycle. The solution was removed and the number of viable *F. solani* quantitated.

American Type Culture Collection.

Proven disinfection efficacy even under rigorous conditions.

HIGHLY EFFECTIVE AGAINST *Acanthamoeba* IN STAND-ALONE TESTING

Given the serious nature of the organism, a 3 log (99.9%) reduction was sought against trophozoites** – the preferred stage for development of a standardised test.⁴



ReNu MultiPlus® solution shows:

- Outstanding efficacy against *Acanthamoeba* trophozoites – even with a high concentration of organic soil to create a more rigorous test condition⁴
- Also shows high cumulative log reductions of *Acanthamoeba polyphaga* and *castellanii* cysts⁴

EFFECTIVELY ELIMINATES *Acanthamoeba* FROM TESTED SILICONE HYDROGEL LENSES⁴

| | <i>Acanthamoeba castellanii</i> | | <i>Acanthamoeba polyphaga</i> | |
|-----------------------|---------------------------------|-----------------|-------------------------------|-----------------|
| | Trophozoites remaining | Cysts remaining | Trophozoites remaining | Cysts remaining |
| ReNu MultiPlus | | | | |
| Lens 1 | 0 | 0 | 0 | 0 |
| Lens 2 | 0 | 0 | 0 | 0 |
| Lens 3 | 0 | 0 | 0 | 0 |
| Lens 4 | 0 | 0 | 0 | 0 |
| Saline Control | | | | |
| Lens 1 | 1,000 | 560 | >3,200 | 1,000 |
| Lens 2 | 3,200 | 100 | >3,200 | 1,800 |
| Lens 3 | 1,800 | 316 | >3,200 | 560 |
| Lens 4 | 1,000 | 1,000 | >3,200 | 1,800 |

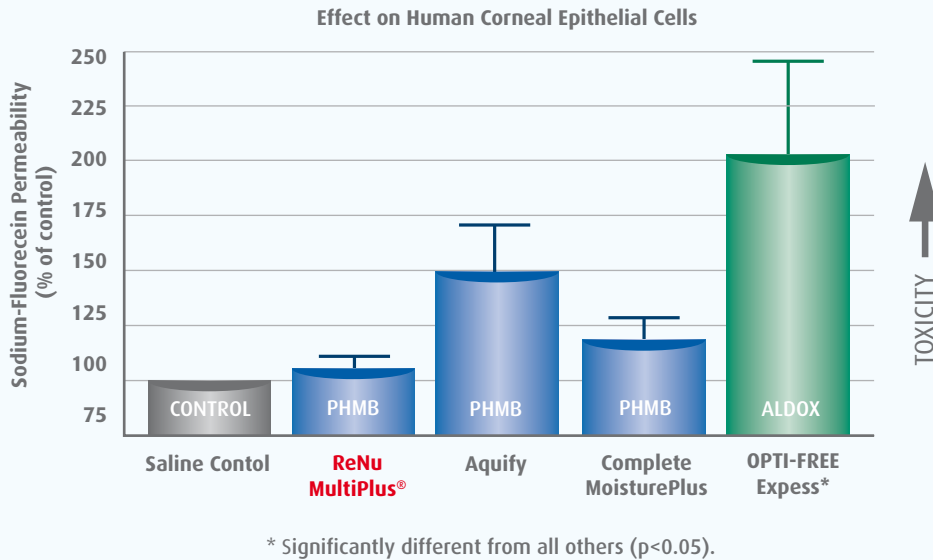
Even under rigorous conditions (high concentration of *Acanthamoeba* and organic soil) ReNu MultiPlus Solution:

- Eliminated 100% of *Acanthamoeba* with 5-second rinse and 4-hour soak time
- Readily removed *Acanthamoeba* – in both trophozoite and resistant cyst stages

** Test follows FDA/ISO stand-alone procedure but is not FDA-required. FDA/ISO stand-alone criteria for effective disinfection are defined as a reduction in the number of bacteria by a minimum of 3 log (99.9%) and a reduction of mould and yeast by a minimum of 1 log (90%) within the recommended disinfection time.

Tests validate the gentleness of PHMB-based solutions.

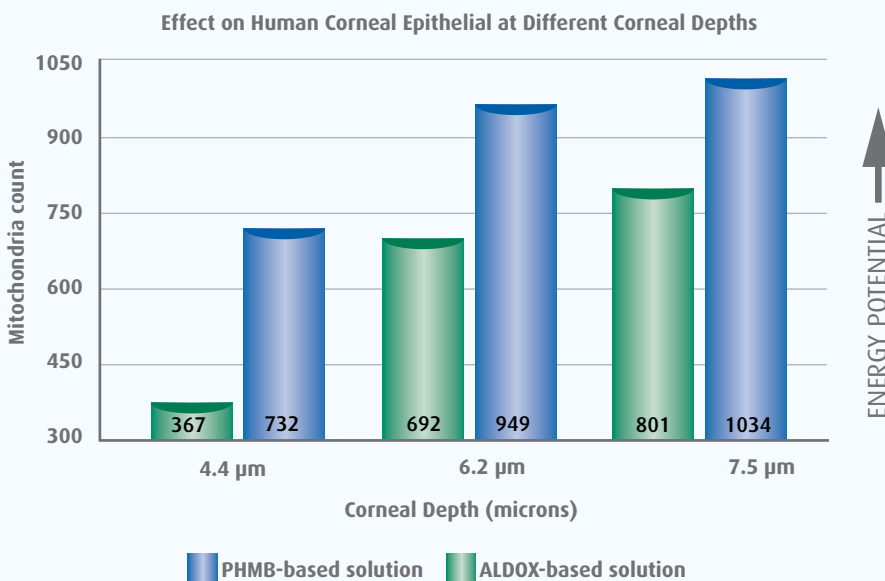
IN VITRO TESTING SHOWS:



- No significant difference between PHMB-based solutions – even when compared to saline control⁵
- The ALDOX-based solution was significantly more damaging to the Human corneal epithelial cells (approximately twice control values)⁵

Test results show that ReNu MultiPlus® solution has a gentle effect on the human corneal epithelial cell line.

GROUNDBREAKING WORK WITH CONFOCAL MICROSCOPY SHOWS:



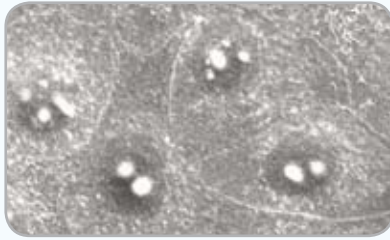
- A statistically significant difference in the number of mitochondria – the “cellular power plants” for the cornea – between cells treated with PHMB-based and ALDOX-based solutions⁶

Corneas exposed to ReNu MultiPlus® solution contain more mitochondria at various corneal depths – indicating the availability of more energy to maintain cell health.

Proven efficacy with unsurpassed biocompatibility.

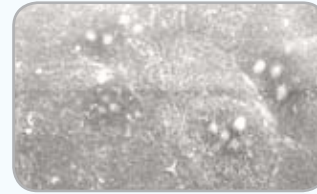
EFFECT ON INTEGRITY OF HUMAN CORNEAL EPITHELIAL CELLS IN CULTURE††

ReNu MultiPlus®



- Cells exhibit similar morphology to HBSS
- Cells demonstrate maintenance of tight junctions

Hanks' Balanced Salt Solution (HBSS)



Opti-Free Express – ALDOX - based



- Cells exhibit extensive morphologic changes compared to ReNu MultiPlus and HBSS
- Cells demonstrate erosion of tight junctions

ReNu MultiPlus Solution demonstrates negligible effects on the tight junctions and cell membranes of human corneal epithelial cells in culture when compared to control.¹

EYE HEALTH OF PATIENTS SWITCHED FROM HABITUAL SOLUTIONS TO ReNu MultiPlus Solution§§

| Events | Habitual Solution | | | | | ReNu MultiPlus | | | | |
|---------------------------|-------------------------|--------------------|-------------------|-----------------------|---|-------------------------|--------------------|-------------------|-----------------------|---|
| | Grade 0 = None | Grade 1 = Trace | Grade 2 = Mild | Grade 3 = Moderate | Grade 4 = Severe (corneal damage) | Grade 0 = None | Grade 1 = Trace | Grade 2 = Mild | Grade 3 = Moderate | Grade 4 = Severe (corneal damage) |
| | % of Eyes in Each Grade | | | | | % of Eyes in Each Grade | | | | |
| Epithelial Edema | 80.3 | 16.0 | 3.2 | 0.5 | – | 87.0 | 10.9 | 1.9 | 0.2 | – |
| Epithelial Microcysts | 87.0 | 12.2 | 0.8 | – | – | 88.6 | 10.6 | 0.6 | 0.2 | – |
| Corneal Staining | 70.2 | 21.4 | 7.8 | 0.6 | – | 77.3 | 18.1 | 4.2 | 0.5 | – |
| Limbal Injection | 49.4 | 34.5 | 13.3 | 2.1 | 0.6 | 56.5 | 33.4 | 9.1 | 0.8 | 0.2 |
| Bulbar Injection | 54.4 | 29.6 | 13.0 | 2.9 | 0.2 | 60.8 | 30.9 | 7.0 | 1.3 | – |
| Arsal Conj. Abnormalities | 56.3 | 27.4 | 13.3 | 2.9 | 0.2 | 61.3 | 25.2 | 10.4 | 2.9 | 0.2 |
| Neovascularization | 64.4 | 25.2 | 8.6 | 1.6 | 0.2 | 68.2 | 24.6 | 5.8 | 1.3 | 0.2 |
| Infiltrates | 94.0 | 5.2 | 0.8 | – | – | 96.3 | 3.1 | 0.6 | – | – |

Grading scale: FDA

- Similar occurrences on slit lamp findings compared with Opti-Free Express and Complete brand Multi-Purpose Solution^{3§§}

†† An in vitro study evaluated the effects of contact lens care solutions on human corneal epithelial cells in culture compared to a control of Hank's Balanced Salt Solution (HBSS). Monolayer cultures were grown and exposed to each solution for 15 minutes. Sodium fluorescein was used to evaluate permeability effects on the monolayer. Additional monolayers were also grown and evaluated after being exposed to each solution for 10 minutes by scanning electron microscopy.

§§ Results of a 62-investigator, multisite clinical study in which hydrogel and silicone hydrogel contact lens wearers were switched to ReNu MultiPlus Solution from their previous lens care system. A total of 390 Opti-Free Express users and 244 Complete brand Multi-Purpose Solution users completed the evaluation. Practitioners completed a slit lamp evaluation at the initial and 2-week visit.

ReNu MultiPlus® – tested for the world your patients live in.

Exceeds international standards

- Superior disinfection against a broad range of pathogens

Effective against a broad spectrum of real-world microorganisms

- Powerful efficacy against clinical isolates of *Staphylococcus aureus* and *Fusarium solani*
- Exceeds international standards against a broad range of ocular pathogens

Exceptional efficacy in non-compliant conditions

- Retains efficacy against clinical isolates even under evaporation and reuse conditions

Highly effective against *Acanthamoeba* in stand-alone testing

- Effectively eliminates *Acanthamoeba* from tested silicone hydrogel lenses

Proven efficacy with unsurpassed biocompatibility

- Demonstrates negligible effects on human corneal epithelial cells
- Maintains overall eye health
- Corneas exposed to ReNu MultiPlus® solution contain more mitochondria at various corneal depths – indicating the availability of more energy to maintain cell health



References:

1. Data on file, Bausch & Lomb Incorporated, Rochester, NY. 2. Levy B. Report on testing from an investigation of *Fusarium keratitis* in contact lens wearers. *Eye & Contact Lens*. 2006;32(6):256-261. 3. Reindel B. Patient satisfaction with no-rub care solutions. *Review of Contact Lenses*, March 2004. 4. R. Borzjani, S. Kilvington: Effect of a Multipurpose Contact Lens Solution on the Survival and Binding of *Acanthamoeba* Species on Contact Lenses Examined With a No-Rub Regimen. *Eye & Contact Lens* 3(11): 39-45, 2005. Stand-alone tests were performed with exposure to 3 separate lots of ReNu MultiPlus® solution in both the absence and the presence of organic soil. Although no FDA/ISO guidelines currently exist for testing lens-care solutions against *Acanthamoeba*, a mean 3 log (99.9%) reduction was sought against *Acanthamoeba polyphaga* (Ros) and *castellanii* (ATCC 30868) trophozoites within the manufacturer's recommended soak time of 4 hours. Silicone hydrogel lens regimen tests were performed with Bausch & Lomb PureVision® contact lenses separately inoculated with each of four separate preparations of *Acanthamoeba polyphaga* (Ros) and *castellanii* (ATCC 30868) trophozoites and cysts in the presence of organic soil. 5. A comparison of the effect of contact lens solutions on sodium fluorescein permeability of human corneal epithelial cells. Cells were treated with test solutions for 15 minutes at 37° Celsius and compared to cells treated with Hanks' Balanced Salt Solution (saline). 6. Fresh bovine corneas were stained with a combination of the cell-permeable mitochondria and nuclear-specific dyes rhodamine 123 and Hoechst 33342 or acridine orange and imaged with a Confocal Laser Scanning Microscope (CLSM). High-resolution X-Y images of corneal epithelium were taken using a Zeiss 510 CLSM at 0.44-0.62 µm Z step and 3-D images of the entire thickness of corneal epithelium were reconstructed. Semi-automated quantitative MatLab software analysis was applied to count the mitochondria in each optical slide. Corneas were treated for 30 minutes with Opti-Free Express and ReNu MultiPlus Solution and were investigated and compared to HBSS control.