

Microbiome-Based Strategy for Preventing and Treating Bacterial Vaginosis in Female Service Members

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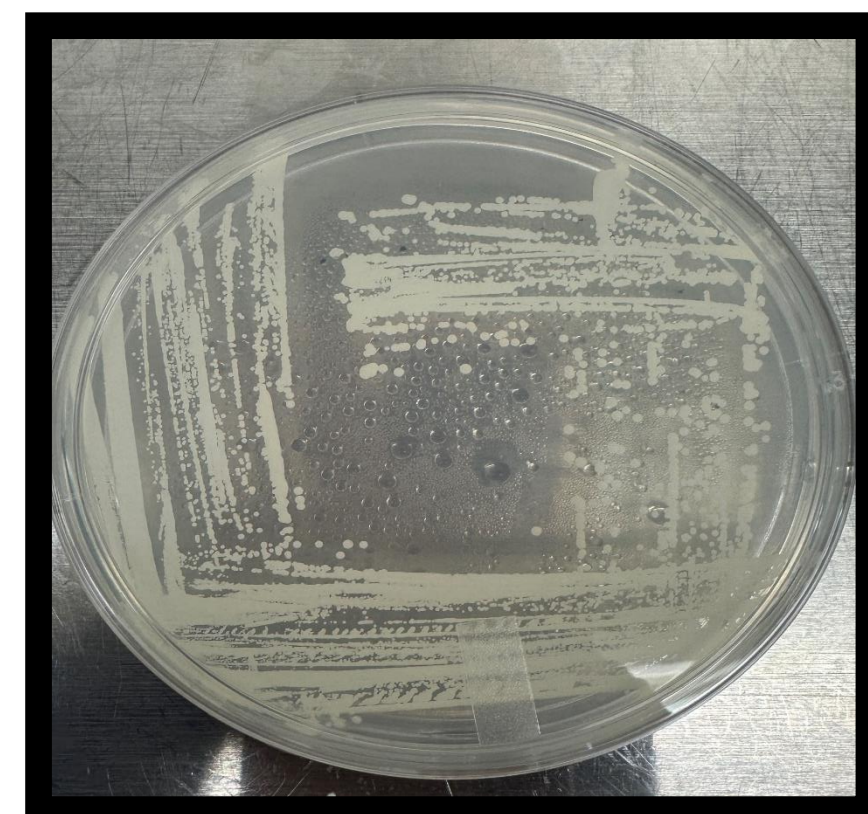
Vaginal infections and urinary tract infections significantly impact women’s quality of life, causing discomfort and functional disruption. Among deployed servicewomen, 30.1% reported vaginal infections and 18.4% reported urinary tract infections, highlighting the need for effective interventions in austere or resource-limited environments. Bacterial vaginosis (BV), a condition characterized by dysbiosis of the vaginal microbiome and overgrowth of *Gardnerella vaginalis*, is associated with increased risk of sexually transmitted infections (STIs), pelvic inflammatory disease, endometriosis, and adverse pregnancy outcomes. Conventional antibiotic treatments have high recurrence rates (>60%) and rising resistance, underscoring the urgent need for novel, microbiome-focused therapies. Our team discovered and isolated a novel, never-before-sequenced *Bacillus* strain that produces a lipopeptide with broad-spectrum antimicrobial activity. This compound was tested against BV-causing *G. vaginalis* and other high-priority, antibiotic-resistant pathogens, including the WHO-designated ESKAPE pathogens. Minimum inhibitory concentration (MIC) assays compared our lipopeptide with vancomycin and tobramycin, and cytotoxicity was evaluated according to ISO-10993 standards. We formulated the lipopeptide into a stable, easy-to-use topical gel suitable for deployment scenarios. The lipopeptide demonstrated potent broad-spectrum activity, neutralizing multiple bacterial and fungal pathogens. For 5 of 6 ESKAPE pathogens tested, 4–9× higher concentrations of vancomycin or tobramycin were required to achieve comparable inhibition, indicating superior efficacy. Importantly, the formulation was non-cytotoxic and maintained microbiome-enhancing properties. Topical gel formulations successfully inhibited *G. vaginalis*, including antibiotic-resistant strains, while promoting microbiome balance, suggesting potential to reduce BV recurrence. A robust microbiome serves as the body’s first line of defense against infection. Our microbiome-based gel represents a safe, effective, and field-deployable alternative to antibiotics, providing both immediate treatment of BV and long-term protection against recurrence. By enhancing microbial balance and addressing antibiotic-resistant pathogens, this intervention has the potential to improve health, readiness, and quality of life for female service members, particularly in austere deployment settings.

Clinical and Military Relevance

- ❑ Vaginal infections and urinary tract infections are increasingly prevalent among deployed servicewomen and adversely affect quality of life.
- ❑ Bacterial vaginosis (BV) is a common vaginal infection caused by reduced *Lactobacillus spp.* and overgrowth of *Gardnerella vaginalis*.
- ❑ More than 30% of women in the Army and Navy reported experiencing vaginal infections, and 18% reported urinary tract infections.
- ❑ We have discovered a novel *Bacillus* species never before identified. This probiotic is effective against several different antibiotic-resistant pathogens.



Penicillin-resistant *N. gonorrhoeae*



Therapeutic *Bacillus* Probiotic Bacteria

Objectives

- ❑ Efficacy testing of a novel probiotic or its extracts against *Neisseria gonorrhea* and *Gardnerella vaginalis* and antibiotic-resistant pathogens including the WHO-designated ESKAPE pathogens.
- ❑ To conduct cytotoxicity testing of the candidate therapeutic based on ISO 10993-5.



Human Microbiome

Evaluation of Antimicrobial Properties

- ❑ Our team has discovered and isolated a novel strain of *Bacillus* bacteria that is a highly effective against deadly, drug-resistant pathogens.
- ❑ We compared the minimum inhibitory concentration (MIC) of our novel antibiotic to two highly effective, widely used antibiotics: vancomycin and tobramycin.
- ❑ Testing was conducted against the ESKAPE and drug-resistant fungal pathogens.

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MIC Testing-ESKAPE Pathogens

Strain	MIC (µg/ml)		
	LP	Tobramycin	Vancomycin
<i>Enterococcus faecium</i>	30	>250	>125
<i>Staphylococcus aureus</i> (MRSA)	30	≥250	125
<i>Klebsiella pneumoniae</i>	30	<250	≥125
<i>Acinetobacter baumannii</i>	>125	≤7.8	>62.5
<i>Pseudomonas aeruginosa</i>	30	<250	>125
<i>Enterobacter cloacae</i>	30	≥125	>125

LP: Lipopeptide isolated from our probiotic that exhibits antimicrobial activity.

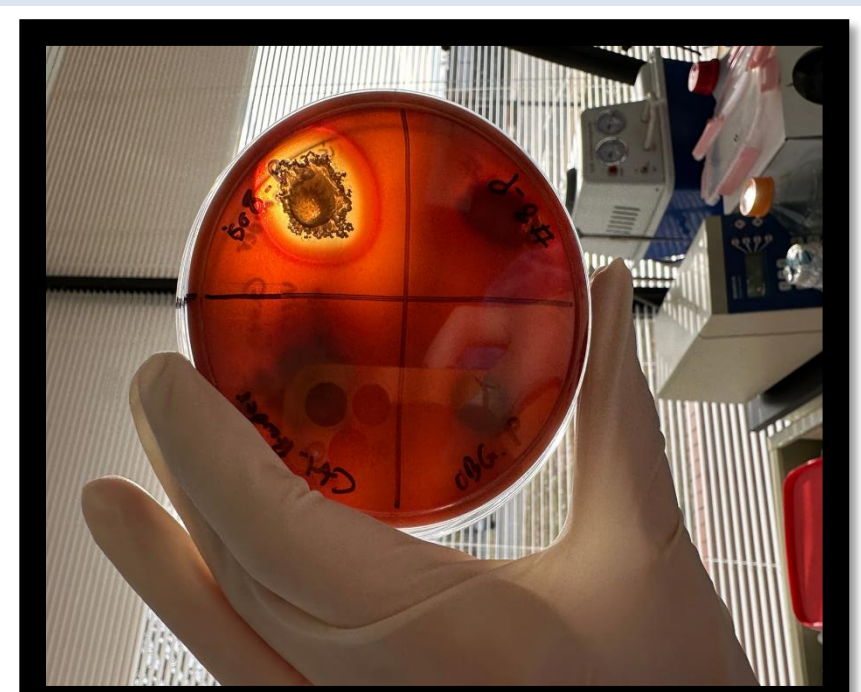
The lipopeptides were successfully tested against 10 bacterial and 15 fungal pathogens. Perhaps the most notable finding of our research was that for 5/6 drug-resistant ESKAPE pathogens, 4-9x more vancomycin or tobramycin was required to neutralize the pathogen hence demonstrating the superior performance of our novel product.

Zone of Inhibition (ZOI) Testing

- ❑ Our team has been focused on the development of novel, safe, non-drug-based therapeutics for sexually transmitted diseases (ex. *Neisseria gonorrhea*) and vaginosis (ex. *Gardnerella vaginalis*).
- ❑ We developed a microbiome-based cream effective against these pathogens.
- ❑ The extract of our probiotic or its extracts can be used to treat infectious caused by drug-resistant *G. vaginalis* and *N. gonorrhoeae*.



Penicillin-resistant *N. gonorrhoeae* (ZOI)



G. Vaginalis ((ZOI)

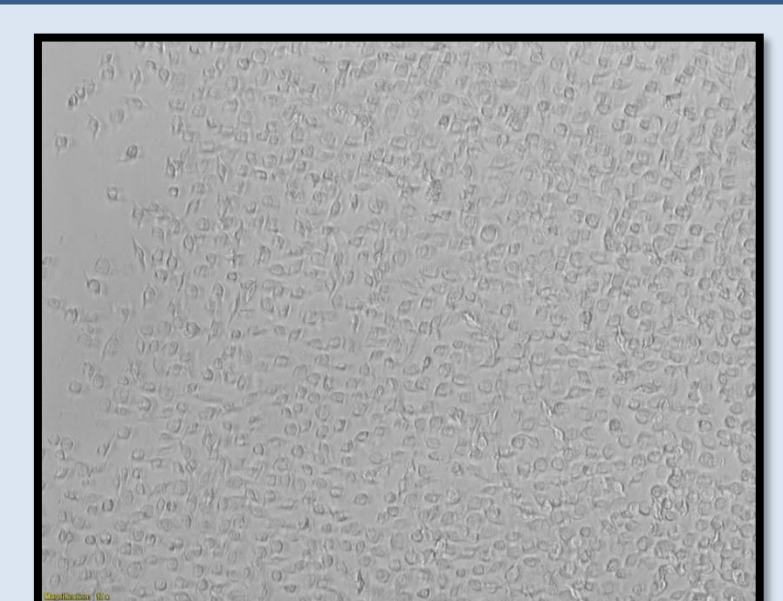
Cytotoxicity Testing



Microbiome Based Solutions are Safer



Mouse Fibroblast (L929 Clone) Cell Line with DMEM Media Only



Mouse Fibroblast (L929 Clone) Cell Line treated with novel therapeutic

Results

Our novel formulation has been shown to be effective against various pathogens including, ESKAPE pathogens, clinical strains of *Gardnerella vaginalis* and penicillin-resistant strains of *Neisseria gonorrhea*.

Conclusion

Our novel microbiome-based formulation is effective against pathogens, including those associated with bacterial vaginosis (BV) and gonorrhea, and represents a safe and field-deployable alternative to conventional antibiotics.

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