U.S. FOOD & DRUG ADMINISTRATION

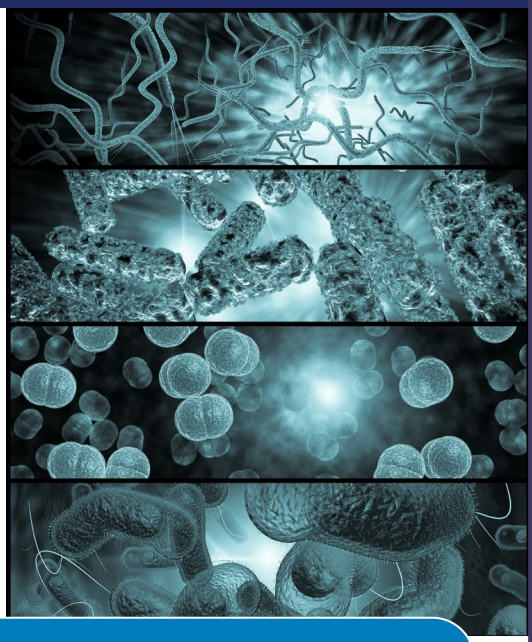
National Center for Toxicological Research (NCTR)

Microbiology

About the Division of Microbiology

Division Mission

Serve a multipurpose function including evaluating the impact of antimicrobial agents, food contaminants, food additives, nanomaterials, and FDA-regulated products on the microbiome; developing methods to detect and characterize microbial contaminants; determining antimicrobial resistance and virulence mechanisms; conducting research to aid FDA in the areas of women's health, tobacco products, and nanotechnology; and improving risk assessments.



Select Microbiology Accomplishments in 2021

Food Safety and Virology: Antimicrobial Resistance and Virulence

- Assessed the contributions of bacterial plasmids to increased virulence and antimicrobial resistance in bacterial pathogens and evaluated factors that lead to dissemination of plasmids between bacteria, which could lead to more difficult-to-treat infections.
- Produced and purified coronavirus spike proteins that serve as important resources for ongoing efforts to examine the interactions of the virus and host cells, and further used computational approaches to predict the impact of spike protein-structure changes on the binding of the proteins to cell surface receptors.
- Carried out studies in partnership with the University of Arkansas at Little Rock to assess the antimicrobial properties of nanostructured aluminum foil surfaces. There are potential applications for nanostructured food-contact surfaces to minimize spoilage and the growth of foodborne pathogens.

Microbiome and Biological Interactions

- Assessed the impact of the exposure of antimicrobial drug residues on the human gastrointestinal (GI) microbiota composition and intestinal permeability. Higher exposures contributed to alterations of the microbiota and intestinal permeability.
- Continued studies on the exposure of xenobiotic compounds — including arsenic, bisphenol AF, and triclosan — on the microbiome and host responses through National Toxicological Program-funded efforts. These efforts are informing risk assessments of the test compounds.
- Evaluated exposure to different nanomaterials on the GI tract and the microbiome. There are limited studies available describing the potential impact of nanomaterials on microbial dysbiosis, inflammatory responses, and epithelial cell permeability following exposure to these types of compounds.

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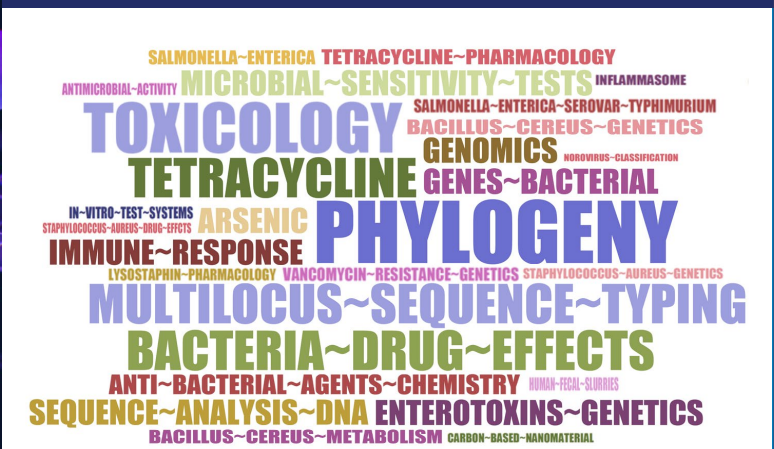

Microbial Contaminants Detection

- Developed and evaluated a simple gene-amplification method for the detection of *Burkholderia cepacia* complex (BCC) in pharmaceutical products. Improved and widely accessible detection methods for BCC are important to limit patient exposure to BCC pathogens that have been linked to multiple disease outbreaks.
- Assessed the impact of different storage conditions of fecal specimens and the corresponding ability to detect the important pathogen *Clostridioides difficile*, which is the cause of difficult-to-treat infections in many patients. The ability to make an accurate diagnosis is key to developing effective treatment strategies for the infections.
- Used sequencing methods to characterize potential bacterial pathogens for both veterinary and human patients.

Ongoing Microbiology Research Projects in 2022

- A Recombinant Coronavirus Spike Protein to Generate Reagents, Study Cell Interactions and Antibody-Dependent Enhancement
- Discovery of Intracellular and Extracellular Signaling Pathways and Mechanisms Contributing to Complement Activation and Coagulopathies Associated with Coronavirus Infections
- Assessment of the Role that the Microbiome May Play in the Toxicity of Xenobiotics
- Multi-Lab Validation of Isolation and Identification of Nontuberculous *Mycobacteria* Associated with Tattoo-Related Skin Infections
- Detection of Microbial Contaminants, Including Anaerobic Bacteria, in Tattoo Inks and Other Related Products
- Establishing Standardized Methods for Sporicidal Efficacy Assessment and Building Up an Efficacy Database of Sporicidal Products to Support FDA's Regulation on Drug Compounding
- Evaluation of Antimicrobial, Antibiofilm and Cytotoxicity Activity of Nanoparticles (Se, V) and Nanostructured Surfaces (Ti, Cu) and Transcriptomic and Proteomic Response of Multidrug Resistant Bacteria
- Evaluation of Tools to Efficiently Assess Antimicrobial Resistance and Pathogenicity-Related Functions of Plasmids in Bacterial Pathogens
- Evaluation of In Vitro Vaginal Tract Models to Assess the Biotherapeutic Potential of *Lactobacillus* Toward Toxic Shock Syndrome Toxin-1 Producing *Staphylococcus aureus*
- Metagenomic Analyses for the Detection of Microorganisms in Non-Sterile Pharmaceutical Products

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