Nelson Labs Bozeman

A Sotera Health company

Testing Services

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Introduction

Since 1991, our independent testing laboratories have conducted investigative and confirmatory studies for both standard and customized in-vitro and clinical studies, providing product safety and efficacy results on a wide range of products, spanning the public consumer and healthcare industries, as well as the food-handling and cosmetic markets.

Our laboratories are trained in: ASTM, AATCC, AOAC, CLSI, and EN standard methods are performed regularly in our laboratories to support EPA, FDA,TGA and HC registrations and label claims. Various regulatory bodies audit our GLP/GCP-compliant laboratories ensuring that Nelson Labs Bozeman (NLB) continues to meet the highest standards in the industry.

Why Test At Nelson Labs Bozeman?

In-House Testing

Nelson Labs Bozeman (NLB) is your one stop location for industry leading efficacy and safety testing. Our Bozeman, MT facility offers 100% in-house testing through our clinical, in-vitro and virology testing labs. With an internal subject recruitment department, in-vivo and in-vitro expertise, and over 30 years of testing experience, we conduct all our testing under one roof. This allows us to offer industry low lead times and industry leading, scientifically sound data for your product.

Industry Leading Study Design

Our Bozeman, MT team prides itself in our multifaceted testing services. Our dedicated clinical and subject recruitment staff are prepared to meet the exact study criteria you need. In conjunction, our In-Vitro and Virology teams offer years of experience in order to efficiently perform even the most complex of studies. Our experience allows us to offer low lead times, standardized methods, and highly specialized custom study design all in an effort to provide you the data you need in the timeline you want.

Experts, Facility, and Network

Nelson Labs Bozeman is the research organization best designed to test your product. Our lab offers one of the largest in-house, multifaceted testing facilities in the industry. Our state of the art facility is further enhanced with a dedicated scientific team boasting decades worth of scientific, regulatory, and product testing experience. We strive to provide top quality testing and customer service, giving you the confidence that our team is prepared to meet any challenge. Nelson Labs Bozeman is the premier location for your product testing needs.

Clinical Testing

Clinical In-Use Testing

Clinical simulated use (CSU) testing has long been a staple of the pharmaceutical and medical device development process. However, due to the extensive benefits and information CSU testing can provide, it is becoming ever more present in all industries with products that are intended for human use. Through CSU evaluations, a product's performance can be measured and evaluated in scenarios that closely resemble its intended use and environment. As a contract research and testing facility, we find that the specificity of the data we can provide when evaluating products in realistic conditions is difficult to replicate by other testing options. Over the past 30 years, our Bozeman, MT team has continuously developed and specialized to offer one of the most comprehensive clinical in use service offerings within the industry. Whether your project calls for R&D assistance for health care patient anatomical compatibility, or regulatory compliant data demonstrating the non-irritability of your cosmetic product, our team has the experience and equipment necessary to get the job done right. Our laboratory team is supported by our expert subject recruitment team, dedicated to recruiting participants that meet your products specific demographic requirements. We offer a comprehensive, one stop testing service to ensure you get the precise data your product needs.

Clinical In Use Testing Services Available For:

Consumer Product Claim Substantiation

Subject Product Claim Support

Anti-Microbial Efficacy Testing

Irritation/Sensitization Testing

Anatomical Compatibility Evaluations

Active Ingredient Interference Evaluations

Skin Care Product and Treatment Testing

Extended Use Product Testing

Ease of Use/Instruction Evaluations

Design Analysis Evaluations

Antimicrobial Efficacy

Skin Contact Antimicrobial Efficacy

Nelson Labs Bozeman has been closely involved in the development and refinement of the healthcare personnel handwash & healthcare personnel handrubs testing methods used to evaluate healthcare personnel handwash/handrub products. Our team has vast experience in the clinical evaluation of skin contact antimicrobial products for both health care and consumer use.

Antimicrobial Persistence Test

Food Handlers Handwash

Healthcare Personnel Handwash & Handrub

Injection Site Protection

Pre-Operative Skin Preparation

Surgical Scrub

Clinical Virology Efficacy Test

In-vivo, clinical efficacy testing using EPA approved coronavirus surrogates (OC43 & 229E) is available. Efficacy testing on sanitizers, rubs, soaps, and other topical disinfectant products is an area of notable expertise held by our team of scientists. Our team's experience with standardized methods (ASTM, EN, AOAC, ISO) provides the highest quality performance on every one of your studies. Custom study designs are also available to ensure you get the exact data you need on the timeline you want.

Oral Antimicrobial Efficacy - Plaque Glycolysis and Regrowth Model (PGRM)

The Plaque Glycolysis and Regrowth Model (PGRM) is a predictive ex-vivo model, which evaluates the clinical effectiveness of antimicrobial (anti-plaque and anti-gingivitis) agents on plaque biofilms in the oral cavity. This model is designed so that treatments can be topically applied in-vivo to dental plaque. Plaque samples are taken from different oral quadrants before and after treatment with an antimicrobial agent. Samples are then placed in appropriate growth medium, incubated at 37 °C for a specified time, and analyzed under standardized conditions in-vitro, using two simple and sensitive endpoints: (1) glycolysis and (2) regrowth inhibition. This model is used to evaluate products such as devices (toothbrushes and other mechanical plaque removal methods) and products with antimicrobial activity (toothpaste and oral rinses). The PGRM is recommended in the FDA's 21 CFR Part 356, Part III for testing of anti-gingivitis and anti-plaque product claims.

Skin Care Testing

The Nelson Labs Bozeman Skin Technology Center offers clinical testing services for both personal and professional skin care products. Standard, validated protocols have been developed to substantiate a wide variety of cosmetic and personal care product claims, as well as claims for prescription and over-the-counter drug products. Additionally, protocols can be custom designed to support specific needs and claims. The high elevation and year-round low humidity of Bozeman, Montana provides an excellent environment for specialized skin studies. The testing we offer includes but is not limited to:

Moisturization/Hydration

Anti-aging

Skin Tone

Acne Spot Reduction

Lesion Reduction

Image Analysis

Transepidermal Water Loss

In-Use Studies

The Bio-instrumentation equipment used includes:

Corneometer: measures moisturization of the stratum corneum layer of the skin using capacitance

Skin pH meter: measures skin pH

Tewameter: measures the TEWL (Trans-epidermal water loss) rate of the skin. The higher the rate, the more damaged the skin

Mexameter: measures redness of the skin

Chroma Meter: measures color on three scales: black white, red green, and blue yellow

Skicon: measures the moisturization content of the stratum corneum level of the skin using high frequency conductance

Sebumeter: measures sebum amounts of the skin or hair

Visia CR: It measures spots, wrinkles, and UV damage

D-Squame – CuDerm: qualitative measurements of skin condition

Irritation and Sensitization

Sensitization Testing

Nelson Labs Bozeman performs sensitization testing by the Modified Draize test in accordance with the FDA/CDER Guidance for Industry, Skin Irritation and Sensitization Testing, (December 1999). Additionally, our Bozeman facility performs testing for skin sensitization to chemicals in natural rubber products with labeling claims of either (1) reduced potential for sensitizing users to rubber chemical additives or (2) reduced potential for causing reaction in individuals sensitized to rubber chemical additives (FDA 1999).

Test Requirements:

The method requires that the product and its vehicle (product without active principle) be tested. During the Induction Phase of testing, test materials are applied to skin sites on the upper back of 200 subjects and patched three times per week for three weeks, the same sites of application each time, for a total of nine applications. Patches remain in place for 48 hours at a time on weekdays and 72 hours on the weekends. Evaluation and scoring of skin reactions are performed and recorded at the time of each patch removal.

The Induction Phase is followed by the Rest Phase of two weeks duration, during which no product applications are performed. Then, during the Challenge Phase, materials are applied to new skin sites on the back and patched for a 48-hour period of exposure, at the end of which, patches are removed.

The challenge sites are evaluated 30 minutes and 24, 48, and 72 hours after the patches have been removed for evidence of allergic reaction.

Irritation Evaluations (Medical Device)

Skin irritation is an important factor contributing to the safety and comfort of medical devices. Medical devices, particularly those requiring repeated contact and adhesion to the skin, may have an irritating effect on the patient's skin that may not become apparent until in-use trials are conducted. Ensuring that the device is compatible with the specific area of the skin, or compatible with damaged or abraded tissue that the device is intended to contact, can help ensure the best experience for patients when using your product. Our dedicated skin laboratory hosts an expert clinical team with years of skin irritation and sensitization testing. Our team's experience spreads from regulatory submission requirements to custom R&D projects, allowing us to offer a detailed skin irritation evaluation of any aspect of your device.

Cumulative Irritation Evaluations

Nelson Labs Bozeman's Skin Technology Center performs clinical evaluations for cumulative skin irritation in accordance with the FDA/CDER Guidance for Industry, Skin Irritation, and Sensitization Testing December 1999.

Study Requirements:

The FDA guidance requires that the drug product and its vehicle (product without active principle) be tested, along with a high-irritancy control material, sodium lauryl sulfate (SLS; also known as sodium dodecyl sulate, or SDS), and a low-irritancy control material, 0.9% saline, by applying small quantities to a single site on the skin of the upper back of 30 ormore subjects each day for 21 days and occlusively patching each site while the applied material is wet.

Materials and Fit Testing

Adhesion and Other Materials Properties

One of the many benefits of medical devices is that their designs can be highly specialized to meet specific health care needs. From this specialization, however, comes equally diverse material properties required of the device. Requirements for adhesives within extended use devices may be a critical point for the device's efficacy. Ensuring that the adhesion, water resistance, and other material properties can withstand the environment of real-life clinical use can be essential to the products success. Our clinical laboratory offers fully custom study design aimed at generating data to give you, and your customers, the confidence that your device is up to the task.

Mask Fit Testing

Negative pressure barrier face coverings (e.g., N95) are devices where the air is purified by being pulled inwards through a filtration media during breathing. By design, the efficacy of these devices relies on the air to pass solely through the incorporated filter. Air leaving through unintended gaps in the respirator's seal compromise its efficacy and may provide lower-than-desired protection. In light of the recent pandemic, and the subsequent increase in importance of facial coverings, ensuring a respirator's appropriate fit has evolved from a matter of personal safety to a matter of public safety. As a result, the ability of a respirator to fit appropriately on the diverse face shapes and sizes of any given community become par mount to that community's public health. For this reason, fit testing of air-purifying, negative pressure respirators should be conducted by manufacturers to measure how well the respirator seals with faces of different shapes/sizes and thus provides confidence that their respirator fully protects users regardless of their face shape/size

Testing Options:

25 Subject Full Panel Study

10 Subject Data Analysis Study

Design Analysis Evaluation

Subjective Claim Support

Subjective Product Claim Support

50-subject Panels for Subjective Product Claim Support

Nelson Labs Bozeman can help generate data to support product claims for in-home use over time. Consumer preference claims can be designed to support product development (fragrance, feel, ease of use, etc.) or they can be designed to compare the product to another product or a placebo control. We can help you determine the best design to generate robust data, whatever your testing goals may be.

Basic Testing Outline:

50-Subject Panel

Up to 15 Questions

Basic Descriptive Statistics

Demographic Information

2 lab visits (one to receive the product, one to return it and answer questionnaire)

An IRB is not required for products that are already marketed. For products that are not marketed or considered a drug, an IRB may be required for an additional fee.

Comfort/Tolerability/Usability

Medical device performance can be evaluated through many different scopes. While ultimately ensuring that the device fulfills the medical needs of patients is paramount, ensuring the device's comfort and usability for both the patient and medical provider can be equally as important. Medical devices that provide excessively uncomfortable or intolerable conditions for patients can hinder the ultimate healthcare goals the device is looking to fulfill. We offer a full clinical panel analysis evaluating subjective elements of products to help maximize the probability of a comfortable and positive experience for your patient and costumer.

In-Vitro Testing

Disinfectant Testing

Nelson Labs Bozeman has over twenty years of experience performing standard (AOAC and EN) disinfectant testing methods, including custom-designed efficacy tests for EPA registrations and FDA 510(k) submissions.

The NLB disinfectant testing laboratory offers clients a complete array of efficacy tests to support bactericidal, fungicidal, tuberculocidal and virucidal label claims. Our extensive library of bacterial, fungal and viral strains allows us to offer our clients more than just basic product efficacy testing. With a focus on providing our clients added value, we can conduct the supplemental efficacy tests that will provide the evidence for label claims that separate you from the competition.

EPA and Health Canada Disinfectant Registration

Our microbiologists perform hard surface disinfectant and sanitizer testing for both EPA and Health Canada guidelines. Whether your product is a germicidal spray, towelette, or concentrate, we can help you with your product testing and labeling claims. These tests are performed according to EPA 810 guidelines for disinfectant and sanitizer testing.

Our extensive microbial library allows us to offer a comprehensive additional claims testing service for EPA and Health Canada registered disinfectants. Our team can help you provide the regulatory data requirements for even the most extensive label claims, including residual efficacy as well as claims against Covid-19 and Monkeypox.

FDA Disinfectant Validation

Disinfectant Validation Studies are an FDA requirement to demonstrate the broad-spectrum antimicrobial efficacy of one or more disinfectant products employed for pharmaceutical and medical device production area qualification prior to use. Test designs are custom to the specific disinfectant(s) chosen by the facility, application method, contact time, surface materials cleaned and relevant microbes (some isolated from the validation site).

Our team of experts will work with you to develop a study-specific GLP protocol, outlining the study step by step to ensure it meets FDA requirements.

Key elements of the study include:

- Specific surface materials and disinfectants associated with your site
- Microbiological testing for both antimicrobial and antiviral efficacy
- QAU oversight and review to ensure data quality

Antimicrobial Efficacy

Nelson Labs Bozeman offers industry leading expertise and study design to generate efficacy data for antimicrobial properties within any application. Our microbiologists are experienced in a wide variety of standards and methodologies in order to create study specific protocols to allow precise, effective, and useful data. Our antimicrobial efficacy services include:

MIC/MBC Test

Minimum Inhibitory Concentration (MIC) and Minimum Bactericidal Concentration (MBC) testing define a test material's potency in terms of the concentration at which it will inhibit growth of (Minimum Inhibitory Concentration, or MIC) or completely kill (Minimum Bactericidal Concentration, or MBC) 1 x 106 (one million) challenge microorganisms during an 18-to-20-hour period of incubated (35 ± 2°C) exposure. The MIC method measures the effect of decreasing concentrations of antiseptic over a defined period of time in terms of inhibition of microbial population growth. The concentration of drug required to produce the effect is defined as the Minimum Inhibitory Concentration, and is normally several hundred to thousands of times less than the concentration found in the finished dosage form.

Time-Kill Test

Time-Kill Kinetic study is the establishment of the rate at which a microorganism is killed by a product as a function of survival data recorded at enough exposure time points such that a graph can be constructed modeling the decline in population over time to a point of extinction. Time-Kill In-Vitro assay tests are referred to as "suspension tests" because a measured volume of the suspension of challenge bacteria or fungi is transferred into a liquid test material, dilute or "neat," to determine how rapidly a challenge species is killed.

Zone of Inhibition

This diffusion test is used to evaluate the static/cidal activity of water-soluble, leachable antimicrobial formulations that will diffuse into an nutrient agar medium. Selected challenge species are inoculated onto the surface of agar plates, and the test materials are laid on top (e.g., surgical dressings) or pipetted into wells cut into the agar. Following incubation, the "zones" of "no growth" surrounding test and control materials are measured for comparison. Additionally, dressings may be transferred to freshly inoculated plates daily for an extended testing period to assess the persistence of antimicrobial activity following repeated challenges.

Safety and Performance

Nelson Labs Bozeman offers a wide array of In-vitro tests to evaluate product performance as an alternative to clinical or animal testing. We offer custom study design to effectively replicate your products real life application in a real life setting.

Preservative Efficacy Test

Preservative Effectiveness Tests, are performed to determine the efficacy of the antimicrobial preservatives added to many pharmaceutical and cosmetic products to prevent contamination over a period of time. Products are challenged with microorganisms either determined by the specific guidance criteria or chosen for relevance to the product, and the product is sampled at different time interval. There are several different guidance documents that address the Preservative Efficacy Testing and criteria such as U.S. Pharmacopoeia <51>, European Pharmacopoeia 5.1.3, International Organization for Standardization (ISO) 11930 and Personal Care Products Council (PCPC) M-3 and M-4. Although these guidance documents are very similar, different criteria are called out in each one

Bovine Corneal Opacity and Permeability (BCOP)

The Bovine Corneal Opacity and Permeability (BCOP) test is an in-vitro method to evaluate chemicals inducing serious eye damage or serious eye irritation. This test method is used to classify substances as “ocular corrosives and severe irritants” as defined by the EPA, EU, and the GHS. This in-vitro test reduces the need for laboratory animals to perform a standard Draize Test.

Skin Model Irritation Testing

The EpiDerm™ Skin Model uses a culture of normal human-derived epidermal keratinocytes that forms a multi-layered model of the human epidermis. This model is mitotically and metabolically active and closely mimics the responses to products exhibited by its in vivo counterpart (RIPT).

Wound Care Testing

Nelson Labs Bozeman has worked with wound dressings for more than 20 years. We offer a way to sell your products for more bottom-line profit to you. We evaluate several different kinds of would dressings, some of which include:

Wounds Dressings that absorb exudate

Wound Dressings that maintain moisture

Wound Dressings that supply moisture for debridement

Antimicrobial properties for the above wound dressings

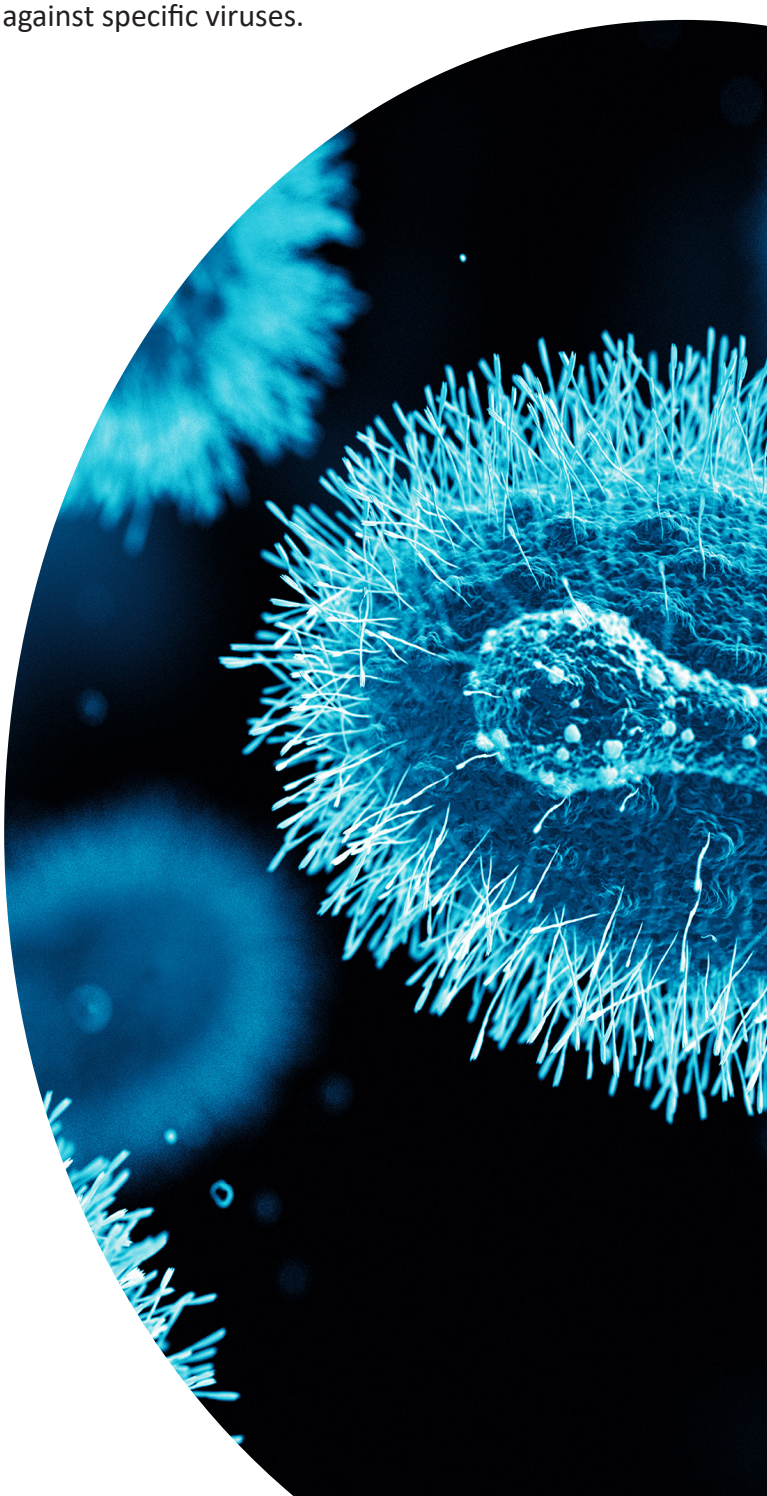
Virology and Biofilm

Virucidal Claims Testing

Nelson Labs Bozeman can assist with new product development, R&D projects, and supporting EPA, FDA, EU, and Health Canada label claims. Combining our virology capabilities with over 30 years of experience in conducting Good Laboratory Practice and Good Clinical Practice studies, we can offer quality study designs to meet your needs. Our personnel, led by Dr. Volha Teagle, are well-trained on the various ASTM, EN, and ISO standard methods and provide clinical and In-Vitro services. The Virology laboratory maintains a collection of over 50 different viral strains and cell cultures which can be used for high-throughput testing. This allows product formulators to test multiple products for efficacy against specific viruses.

BioSafety Level - 3 Virucidal Efficacy

Our In-Vitro and Virology laboratories have long been a pillar of our disinfectant and anti-microbial efficacy services. We have now taken that offering to the next level through our BSL-3 lab. Our expert team, lead by Virologist Volha Teagle, Ph.D., is conducting our ISO 17025 certified testing against BSL3 pathogens; including **SARS-COV-2 and Monkeypox Virus**. Our experience in study design and multi-agency regulatory processes prepares us to produce the precise data you need in the timeline you want.



Regulatory Virucidal Claims Testing

These tests are designed to provide virucidal efficacy data for disinfectant products challenged with various viruses. Testing is conducted as specified by the U.S. Environmental Protection Agency requirements set forth in the Pesticide Assessment Guidelines, Subdivision G: Product Performance. We offer a wide array of challenge organisms, including BSL-2 surrogates and BSL-3 emerging pathogens.

Treated Surfaces and Fabrics Virucidal Testing

The pandemic has resulted in an increase of manufacturing materials used with inherent antimicrobial properties. Treated fabrics and plastics require efficacy evaluation supporting their antimicrobial claims. Our team offers a comprehensive service with experience on a wide variety of carriers and surfaces to meet the precise data requirements for your products needs.

Sterility Assurance

Viral Clearance

Nelson Labs Bozeman's Virology lab performs Viral Clearance studies to provide safety data for bio-pharmaceutical products or medical devices that are derived from human or animal tissues. We design Viral Clearance studies in compliance with the relevant guidelines and standards such as Q5A Viral Safety Evaluation, ISO 22442-3, and the European Note for guidance on virus validation studies. To verify and provide safety data for bio-pharmaceutical products or medical devices that are derived from human or animal cell lines. These data are critical for companies who manufacture bio-pharmaceutical products or medical devices that utilize human or animal cell components to ensure the removal or inactivation of viruses. Viral Clearance studies verify virus inactivation or removal and validate safety of manufacturing processes and final products.

Viral Barrier Penetration

Our facility offers viral penetration evaluations across a variety of materials. We can help you determine your products packaging or protective barriers ability to prevent viral contamination. Custom study design is available to help emulate your products performance in a simulated environment.

Blood Contact Reusable Medical Device: Cleaning & Disinfection Procedure Validation

Nelson Labs Bozeman conducts the FDA-required validation of cleaning and disinfection procedures based upon AAMI TIR12:2010 "Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers". Each evaluation will include the following FDA requirements:

- Selection of an EPA-approved registered cleaning and disinfection product that does not result in the physical deterioration of the device overall, or deterioration of any device component, such as the housing or touchpad buttons.
- Demonstration using the standard ASTM E1053 and ASTM E2362 tests that the disinfection protocol is effective against Hepatitis B virus and other blood-borne viruses.
- Demonstration that the device is robust to cleaning and disinfection procedures after multiple cleaning and disinfection cycles.
- Description of how the cleaning and disinfection procedures affects device ports and sensors.
- Confirmation that the disinfectant does not cloud the face/display the device and does not corrode or erode the plastic housing or buttons.
- GLP Protocol with acceptance criteria.

Biofilm Testing

A biofilm is a community of microorganisms embedded in a slimy matrix which can attach to various surfaces. A great diversity of species has been found in biofilms, including bacteria, viruses, and fungi. Biofilms can exist on inert surfaces such as glass, plastic, and metal, but can also use plant and animal tissues as a substrate. Nelson Labs offers services to companies that want to substantiate anti-biofilm claims for their products, and we can assist you in test design and execution. Using ASTM methods, customized experiments, and regulatory insight, NLB can help you generate the data needed to support your anti-biofilm claims, such as biofilm kill, removal, and prevention

Testing Capabilities:

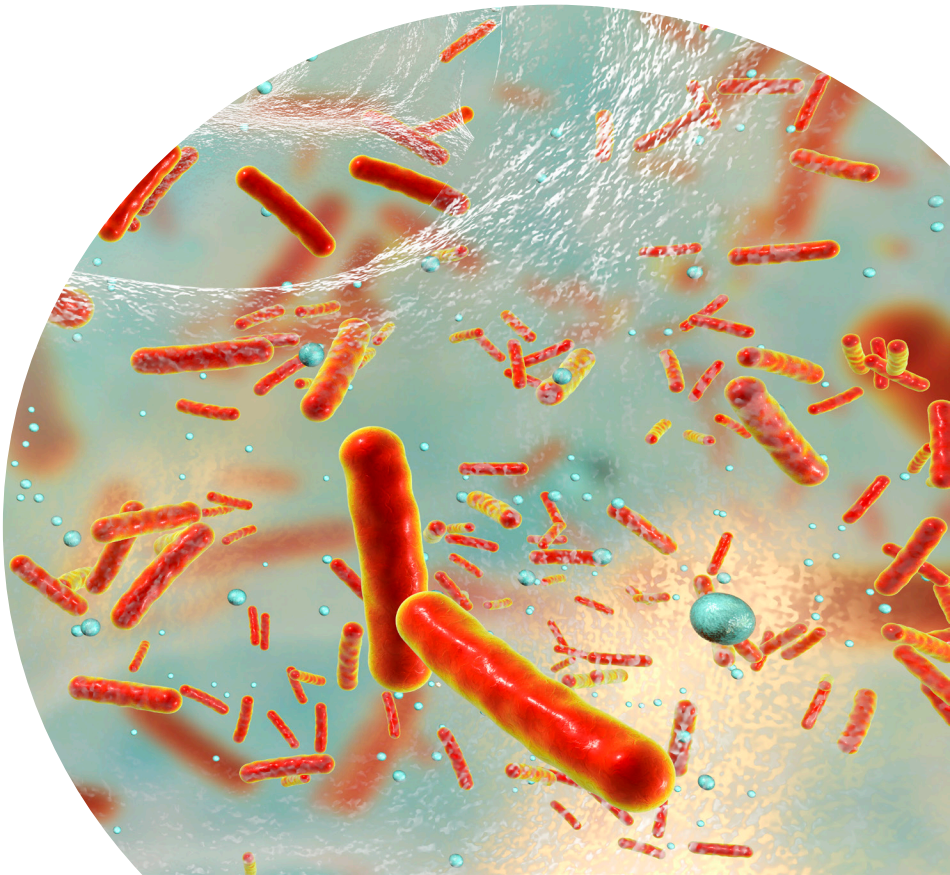
- Biofilm disinfectant efficacy testing
- A chronic wound biofilms and dressings
- Oral biofilms
- Medical devices
- Drug synergy (modified checkerboard assay)
- Biofilm in treated water systems

Biofilm Test Methods:

- CDC Biofilm Reactor Protocol ASTM E2562 and Single Tube Method ASTM E2871
- Drip Flow Reactor Protocol ASTM E2647
- Modified Colony/Drip Flow Reactor Protocol
- Minimum Biofilm Eradication Concentration (MBEC) Testing ASTM E2799
- EPA Protocols (MB-19, MB-20)
- Zero-Shear (Static) Colony Biofilm Method

Organisms:

- Pseudomonas species
- Staphylococcus and MRSA species
- Candida species
- Clinical samples
- Environmental samples
- Donated saliva
- Antibiotic-resistant strains
- Additional microorganisms (inquire)



Company Information

About Nelson Labs Bozeman

Since 1991, our independent testing facility has conducted investigative and confirmatory studies for both standard and customized in-vitro and clinical studies, providing product safety and efficacy results on a wide range of products, spanning the public consumer and healthcare industries, as well as the food-handling and cosmetic markets. We are recognized as the leading authority for topical antimicrobial testing.

Our laboratories are trained in ASTM, AATCC, AOAC, CLSI, and EN standard methods that are performed regularly in our laboratories to support EPA, FDA, TGA and HC registrations and label claims. Various regulatory bodies audit our GLP/GCP compliant laboratories ensuring that Nelson Labs Bozeman continues to meet the highest standards in the industry. We are very astute in statistical design and offer a wide array of statistical analysis depending on our client's needs. We constantly scan the competitive environment to assist our customers in gaining a strategic competitive advantage in their respective industries.

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