



biInique

The Mycoplasma Testing Experts
Supporting Your Therapeutic's Journey
from Discovery to Commercialization

**Test Better,
Together.**

About Us

Bionique Testing Laboratories LLC is a leading Contract Research Organization with GMP FDA-registered facilities that have been providing the highest quality mycoplasma testing services for the biopharmaceutical and life science industry for more than 30 years. Located in Saranac Lake, NY, Bionique partners with clients to support their needs as they work from discovery to commercialization. Through analytical testing methods, development and validation of rapid microbiological methods, and regulatory and compliance consulting services, Bionique strives to provide high-quality support and technical expertise for biopharmaceutical and cell therapy products.

OUR MISSION

To protect the health and safety of patients by providing expert analytical testing services for biopharma products.

OUR VISION

To be the best-in-class provider of mycoplasma and biosafety testing services that offers unparalleled technical expertise with a first-rate customer experience.

OUR PROMISE

To provide our customers with technical capabilities, outstanding service, and regulatory knowledge to ensure their products are free of mycoplasma contamination.

Our focus is safety.

Through traditional compendial testing, real-time PCR assays, and emerging rapid microbial methods, Bionique offers a comprehensive suite of mycoplasma detection services that assure the safety of your life-changing therapeutics.

Commitment in our DNA.

Bionique's top-tier scientific and quality staff is committed to reliably testing your product and supplying certificates of analyses with industry-leading turnaround times to aid the timely release of your critical biopharmaceutical product.

Your trustworthy partner.

We are recognized as subject matter experts in mycoplasma analytics, equipped with cutting-edge alternative methods, extensive regulatory knowledge, and robust testing protocols that you can trust from cell line to lot release.

Serving Clients Worldwide Including:

- Biopharmaceutical/Biotechnology
- Cell therapy manufacturers
- Raw material suppliers
- Cell Development and Manufacturing Organizations (CDMOs)
- Clinical Research Organization (CROs)
- In Vitro Diagnostic (IVD) manufacturers
- Academic research institutions
- Government entities (e.g., CDC)

Our Services

Your Products	Starting Materials	Our Mycoplasma Testing Assays and Services
 Commercial Products	<ul style="list-style-type: none"> • Biopharmaceuticals • Biosimilars • Cell and Gene Therapies • Vaccines 	<ul style="list-style-type: none"> • FDA Points to Consider Method (M-700) • Harmonized USP <63> Mycoplasma Test (M-1400/M-1450) • Real-Time PCR w/ Broth Enrichment (M-1500/M-1500Q)
 Clinical Trial Materials	<ul style="list-style-type: none"> • Biopharmaceuticals • Biosimilars • Cell and Gene Therapies • Vaccines 	<ul style="list-style-type: none"> • FDA Points to Consider Method (M-700) • Harmonized USP <63> Mycoplasma Test (M-1400/M-1450) • Real-Time PCR w/ Broth Enrichment (M-1500/M-1500Q)
 Cell Lines	<ul style="list-style-type: none"> • Incoming Cell Lines • Master Cell Banks • Working Cell Banks 	<ul style="list-style-type: none"> • DNA Fluorochrome Staining Assay with Indicator Cell Line (M-150) • Multi-Media Direct Culture Method with DNA Fluorochrome Staining (M-250) • FDA Points to Consider Method (M-700) • Harmonized USP <63> Mycoplasma Test (M-1400/M-1450) • Real-Time PCR w/ Broth Enrichment (M-1500/M-1500Q)
 Raw Materials	<ul style="list-style-type: none"> • Sera • Culture Media • Cell Culture Components/Supplements 	<ul style="list-style-type: none"> • Large Volume Barile Method (M-300) • Large Volume Barile Method with DNA Fluorochrome Staining Assay (M-350) • Harmonized USP <63> Mycoplasma Test (M-1400/M-1450)
 Assay Development, Validation & Transfer	<ul style="list-style-type: none"> • Biopharmaceuticals • Biosimilars • Cell and Gene Therapies • Vaccines 	<ul style="list-style-type: none"> • Custom PCR Assay Development • Phase-Appropriate Validation Studies • Tech Transfer • Technical and Regulatory Expertise • External Validation of New Platforms
 Reference Materials	<ul style="list-style-type: none"> • Biopharmaceuticals • Biosimilars • Cell and Gene Therapies • Vaccines 	<ul style="list-style-type: none"> • Mycoplasma Control and Reference Standards • Mycoplasma Antigen Preparations

Assay Development, Validation and Transfer

Bionique has a GMP-registered site that is fully dedicated to assay development services, with a focus on validation of novel, rapid molecular-based technologies for mycoplasma detection. Our team of R&D validation experts is here to support your molecule's journey towards clinical and commercial success by developing and implementing a validation strategy for an alternative method tailored specifically for your unique CMC needs.

For release testing of bulk harvest, clinical lots, and commercial products in the US, EU and other global markets, we provide a phase-appropriate approach to the development, validation and technical transfer of analytical methods for mycoplasma detection.

Test Better, Together.

Our routine analytical services and our custom method development and validation studies are available for traditional culture-based methods, real-time PCR assays, and the emerging applications of rapid microbial methods.

From discovery to commercialization of your therapeutic, we partner with you to test cell banks, raw materials, unprocessed bulk harvest, and final drug product modalities ranging from monoclonal antibodies to cell and gene therapies.



Mycoplasma Testing



Scientific Expertise



Collaboration

PART OF THE BIOSAFETY TESTING SERVICES DIVISION OF ASAHI KASEI BIOPROCESS

Asahi Kasei Bioprocess, a division of Asahi Kasei Medical, supplies innovative bioprocessing tools and services that enhance the safety, manufacturing efficiency, and purity of modern biotherapeutics and pharmaceuticals. With offerings in purification, fluid management solutions, and pathogen safety testing services, Asahi Kasei Bioprocess provides a growing set of technologies that enable manufacturers of regulated therapeutics to safely and efficiently produce medicines that patients can trust.



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