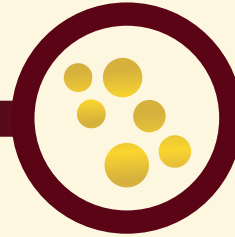




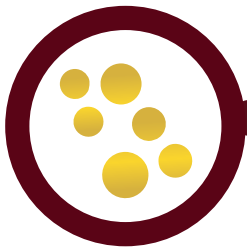
## Microbiology Laboratory

Reliable & consistent results,  
our top priorities.





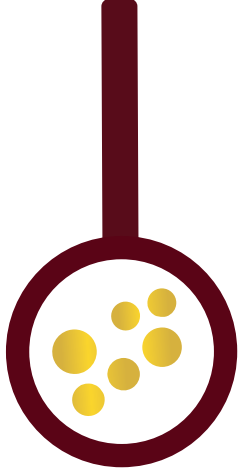
**M-BioLabs** is your partner in maintaining a microbial monitoring program for compliance with USP <797>.



# USP <797>


USP<797> is designed for healthcare institutions, pharmacies, and other related facilities that prepare compounded drugs. The environmental monitoring of these facilities and the microbial evaluation of staff's aseptic techniques while compounding sterile preparations are critical to patient care.





## **Not subject to USP standards?**

For clients that are not subject to USP standards, our environmental laboratories analyze air, water, solids, and surface samples for the presence of bacteria and yeast/molds.

A close-up photograph of a laboratory setting. A person wearing a white lab coat and green nitrile gloves is using a blue pipette to transfer a red liquid from a petri dish. The petri dish is held in the left hand, and the pipette is held in the right hand. The background is slightly blurred, showing other laboratory equipment like a rack of test tubes and another petri dish.

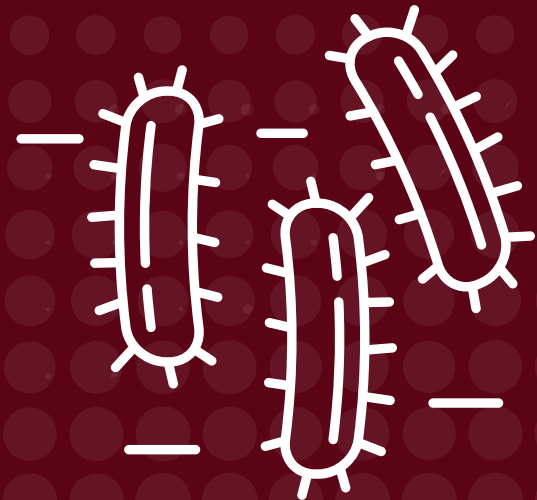
"Science knows no country  
because **knowledge belongs to  
humanity**, and is the torch which  
illuminates the world."

- Louis Pasteur

Compounding sterile preparation pose the risk of microbial contamination to patients.

- ④ High costs for testing.
- ④ Slow turnaround time.
- ④ Difficulty in acquiring media.
- ④ Lack of accurate identification of organisms to properly mitigate.
- ④ Higher liability.
- ④ Lack of accreditation/equipment to determine genus and species.
- ④ Development of machinery, training and equipment expense.
- ④ Atrophy of space and time consumption for staff testing in-house.
- ④ Improper storage/handling of the media plates. Incorrect incubation settings.
- ④ Lapses in cleaning and garbing procedures.

# The Problem



**M-BioLabs** staff is skilled and qualified in analysis of environmental and personal hygiene evaluation samples that include incubation, enumeration and identification of bacterial and fungi in air, surface, gloved fingertip and media-fill samples.

④ Budget prices.

④ Quick turnaround time.

④ Media offers for testing needs.

④ Valid and consistent results.

④ Customized reports.

④ Certified laboratory.

④ Accurate organism identification with Mass Spectrometry Capability.

④ Commitment to superior analytics.

④ Commodious testing ground and qualified professionals.

④ Proper handling of Chain of Custody (COC) and media plates.

④ Assistance to maintain compliance with USP <797>/<825>.

④ Sterility testing.

# The Solution





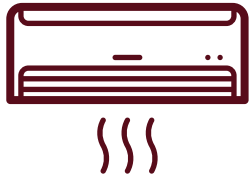
# Why M-BioLabs?

M-BioLabs has an involved and relentless staff. Our lab is constantly researching new methods to best serve clients and stay on top of practices needed within the industry. Always willing to accommodate customer's needs and invest in new equipment, accreditations and technology.



# Capabilities

## Air Testing



## Surface Testing



## Water Testing



## Services

- ◆ Incubation, enumeration and Identification of bacteria, yeasts and molds.
- ◆ Sterility Testing of Product
- ◆ Growth Promotion
- ◆ Biological Indicators
- ◆ Membrane Filtration
- ◆ Test for Specified Microorganisms
- ◆ Gloved Fingertip Samples

## Compliances

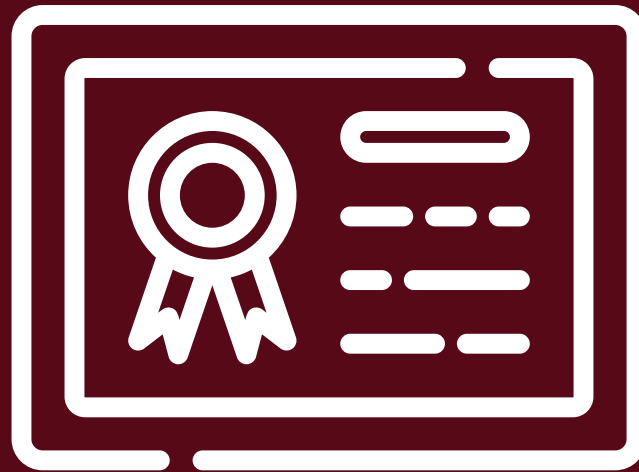
- ◆ USP<797>
- ◆ USP<825>
- ◆ USP <61>
- ◆ USP <62>
- ◆ USP<71>

## Medias

- ◆ Media Plates
- ◆ Media Fills
- ◆ Media Paddles
- ◆ Swab Samples

\*We offer media for your needs. Contact us for stock availability.

# Accreditations & Certifications



# ISO 17025 ACCREDITED

M-BioLabs is accredited by PJLA to perform incubation, enumeration and identification of viable samples meeting the standards and following techniques enforced under USP<797> and USP<825>.

		<b>PERRY JOHNSON LABORATORY ACCREDITATION, INC.</b>
<h3>Certificate of Accreditation</h3>		
<i>Perry Johnson Laboratory Accreditation, Inc. has assessed the Laboratory of:</i>		
<b>M-BioLabs, Inc.</b> 12815 Wetmore Road, San Antonio, TX 78247		
<i>(Hereinafter called the Organization) and hereby declares that Organization is accredited in accordance with the recognized International Standard:</i>		
<b>ISO/IEC 17025:2017</b>		
<i>This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system (as outlined by the joint ISO-ILAC-IAP Communiqué dated April 2017):</i>		
<b>Microbiological Testing</b> <i>(As detailed in the supplement)</i>		
<small>Accreditation claims for such testing and/or calibration services shall only be made from addresses referenced within this certificate. This Accreditation is granted subject to the system rules governing the Accreditation referred to above, and the Organization hereby covenants with the Accreditation body's duty to observe and comply with the said rules.</small>		
<b>For PJLA:</b>		
	<b>Initial Accreditation Date:</b> April 21, 2017	<b>Issue Date:</b> May 12, 2023
<b>Tracy Seerssen</b> President	<b>Accreditation No.:</b> 94315	<b>Expiration Date:</b> August 31, 2025
<b>Perry Johnson Laboratory Accreditation, Inc. (PJLA)</b> 755 W. Big Beaver, Suite 1325 Troy, Michigan 48064	<b>Certificate No.:</b> L23-286	<small>The validity of this certificate is maintained through ongoing assessments based on a continuous accreditation cycle. The validity of this certificate should be confirmed through the PJLA website: <a href="http://www.pjla.com">www.pjla.com</a></small>
<p>Page 1 of 2</p>		

## Reference:

About M-BioLabs. (n.d.). M-BioLabs, Inc. <http://mbiolabs.com/>


Blog. (2020, February 26). Environmental Health Engineering. <https://eheinc.com/blog/sterile-drug-compounding-contamination-what-facility-managers-need-to-know-and-how-to-maintain-compliance/>


NCBI – WWW Error Blocked Diagnostic. (n.d.). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3627035/>

State Regulation of Compounding Pharmacies. (n.d.). <https://www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx>

USP 797 Cleanroom Guidelines | Standards for Sterile Compounding Labs. (n.d.). <https://www.portafab.com/usp-797-sterile-compounding-guidelines.html>

## Contact us:

 877-659-4353

 210-202-5750

 [inquire@mbiolabs.com](mailto:inquire@mbiolabs.com)

 [/company/m-biolabs-inc](https://www.linkedin.com/company/m-biolabs-inc)

## Address:

12815 Wetmore Road  
San Antonio, TX 78247

# THANK YOU

Visit us at <http://mbiolabs.com>