

BIOMÉRIEUX

THE DIRTY SECRETS OF ASPERGILLUS

Protect your product, profits, and consumer health & safety.



PIONEERING DIAGNOSTICS

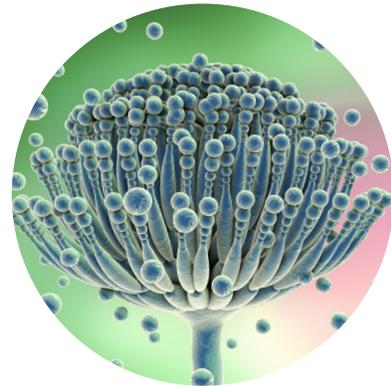


Preface

From the very origins of cannabis growth through sample preparation, *Aspergillus* microbial contamination is a constant pain point. This means that laboratories and indoor cultivation facilities need to meet and exceed best practices to identify and remediate microbial contamination as soon as possible and continue to guarantee a safe product through compliance testing.

In an industry where compliance is a dominant influence, navigating and understanding cannabis microbiology can be a tall order, but it does not have to be daunting. Utilizing education, research, and knowledge of *Aspergillus* and microbial contamination and leveraging industry experts will allow you to keep *Aspergillus* under control.

Knowing *Aspergillus* risks and managing those risks, combined with understanding the regulations and partnering with a good laboratory, can mean the difference between success and failure or profitability and disaster. For laboratories, microbiology is often an afterthought while analytical chemistry makes up a majority of regulatory compliance testing. There is a big difference between the two. Understanding appropriate techniques, considering turnaround time pressure, and hiring the right personnel are the keys to running a successful and smart microbiology laboratory. Whether you're in the cultivation facility keeping an eye on your valuable crops or a laboratory technician in a cannabis compliance production laboratory seeking to streamline operations, identifying and mitigating microbial contamination is an essential skill to have, and where microbiology brings the greatest value in protecting your product, your customers, and your brand.



With cannabis often being consumed through inhalation, this adds an additional risk to human health and safety, as certain contaminants are dangerous and even deadly, especially when introduced to the lungs.

Aspergillus is a tricky fungus; creating more threats to your crop, production, profitability, and human health. Let's pull back the curtain on *Aspergillus* to reveal its secrets in order to establish a clearer path to dominate it, improve profitability, quality, and enhance health and safety.

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Why care about *Aspergillus*

Aspergillus is ubiquitous – it is found everywhere including the soil, air, decaying vegetation, seeds, and grains. It is a common mold that thrives in oxygen-rich plant environments, grows in dead and decaying material or harvested crops, at a wide range of temperatures and in low relative humidity. Cannabis plants are extremely susceptible as they provide a good ecosystem to support *Aspergillus* because they are great sources of water, carbon matter, and sugar which aid the survival of mold. Whether your product is grown indoors or outdoors, *Aspergillus* can take its toll.



GROWN
INDOORS

**Controlled environment
allows *Aspergillus* to grow,
thrive, and become epidemic.**



GROWN
OUTDOORS

***Aspergillus* better
managed due to natural
checks and balances.**



Wet cannabis /
unprocessed (80% water)



Mold colonizes
plant matter



Fungal spores are now mobile,
airborne, and on surfaces

Controlled temperature, high
humidity, acidic environment
help *Aspergillus* germinate
and thrive



Live cannabis plants utilize their natural defenses on the constant onslaught of pathogens including *Aspergillus*. Once a plant is harvested, it can no longer defend itself and becomes susceptible to lurking *Aspergillus* waiting to attach and attack.

Aspergillus that may be lurking in a facility can lead to failed compliance tests, loss of product, decreased profitability, and human health risks.

It's widely known that *Aspergillus* constitute threats to plants; less commonly known is that it can pose a health threat to humans. *Aspergillus* spores can be inhaled from the environment or from consuming contaminated cannabis. The spores colonize in the lungs and can lead to the formation of a fungus ball. While sometimes asymptomatic, it can cause chronic coughing-up of blood and even fatal bleeding. It can also cause lung diseases such as aspergillosis, aspergilloma, and different hypersensitivity diseases such as allergic asthma, hypersensitivity pneumonitis, and allergic bronchopulmonary aspergillosis. These dangers influence the need for strict and stringent cannabis regulations reflected with most states mandating a zero tolerance (less than 1 CFU/g) for *Aspergillus* spp. compliance, particularly against the highest risk and most toxic species such as *A. niger*, *A. fumigatus*, *A. flavus*, and *A. terreus*. In May 2020, the United States Pharmacopeia (USP) published a scientific paper with recommendations for cannabis testing which included *A. flavus*, *A. fumigatus*, *A. niger*, and *A. terreus*. We continue to see many regulatory bodies include *Aspergillus* testing within regulations for consumer health and product safety against this threatening mold.

Aspergillus is a sneaky opportunist with many secrets – all of which seem focused on sabotage, posing a threat to your entire harvest leading to costly remediation, possible lawsuits, or the destruction of your brand.

With the high risk of *Aspergillus* to human health and safety, this could lead to consumer safety issues and lawsuits. This doesn't have to happen. You can protect your brand image, improve compliance, and increase your profitability while protecting consumers. Knowing the secrets of *Aspergillus* and mitigating risk increases are essential.

“Moldy flower can sink a brand’s reputation as well as its business. Expensive mold recalls of unsafe product can take down a company in this highly competitive cannabis field. Brands must proactively address moisture control before capturing headlines for the wrong reasons. And putting consumers at great risk.” – Rachelle Gordon, on behalf of Boveda®



The 5 Dirty Secrets of *Aspergillus*

Provided the ideal environment such as indoor cultivation sites or warm laboratories, *Aspergillus* thrives and rapidly multiplies. To protect your product, profitability, and consumer health and safety it's essential to know 'The Five Dirty Secrets of *Aspergillus*' and how to prevent it from being a concern in your cannabis operations from indoor cultivation to the laboratory.

1) *Aspergillus* hides and thrives. Given the chance, *Aspergillus* will multiply to create devastation to your operations exponentially. It is survival of the fittest and it will go to desperate measures to ensure it survives. It conceals itself in many places, especially on porous materials like unfinished wood, ceiling tiles, carpet, and insulation, and thrives on organic or decaying materials including growth mediums such as soil, coco coir, and the harvested cannabis plant. It waits to attack the cannabis plant postharvest when the plant's defenses are no longer a barrier of protection. *Aspergillus* then leverages the cannabis plant's physiology to be even sneakier. *Aspergillus* spores bind to the sticky terpenes on cannabis flower providing a secure host for *Aspergillus*.

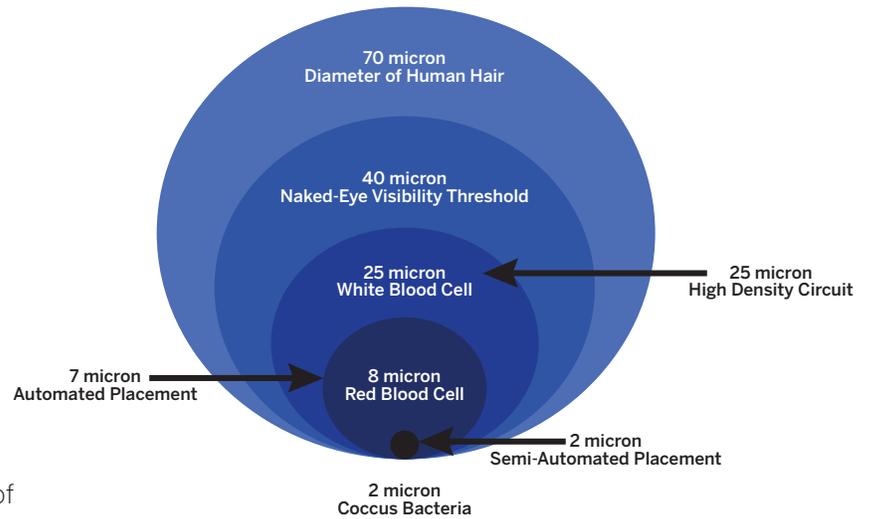
2) It only takes one. One spore can exponentially grow under the ideal conditions leading to a higher likelihood of a failed test. Higher temperatures, higher relative humidity, and porous materials are commonly found within indoor cannabis growing rooms, giving *Aspergillus* optimal conditions for exponential growth. Mold spores are much smaller than a cannabis seed and make it virtually impossible to see if there is contamination within your facility.



3) If you can't see it, it's still there.

Have you ever had a loaf of bread grow mold? If so, the mold is very noticeable with its distinct colors and 'mold fuzz.' Many molds have similar characteristics easy to visualize. *Aspergillus* contamination is not typically visible on cannabis, increasing the challenges of identifying a problem or confirming a problem that requires remediation. To complicate things further, *Aspergillus* spores are not visible to the naked eye at 2.0-3.0 microns; ¼ of the size of a human red blood cell and 45 times smaller than the diameter of a human hair. Not visible, but still very present.

Aspergillus spores are not visible to the naked eye



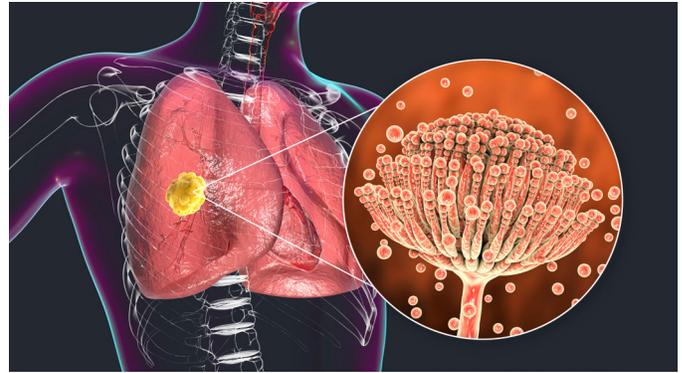
4) Once you have it, you have it. *Aspergillus* is not easy to eradicate; they are one of the more persuasive molds in North America and they are adaptable and mutate to survive and grow. *Aspergillus* does not discriminate; it's seeking survival and will do everything to live.

Sometimes, when cleaners are used to control the mold, *Aspergillus* adapts and the cleaner no longer functions effectively. This is why routine volatile and surface chemical treatments are ideal, and changing regimens periodically is advisable as it creates a less hospitable environment for growth.

Aspergillus is a risk for the entire industry. You are not alone. No facility wants to be marked by a problem that could have negative implications and stigmas. The conversation needs to move past contamination stigma and foster education and collaboration to expand proactive approaches and remediation practices.



5) Aspergillus can be deadly. Cannabis is frequently inhaled by consumers providing *Aspergillus* a direct pathway to the lungs. There is no cure - prevention is critical. Aspergillosis has several forms of which mostly develop in lungs and can develop in the ear canals and sinuses. Aspergillosis can become very aggressive and rapidly spread into the bloodstream accessing the brain, heart, liver, kidneys, and other organs.



As a cannabis cultivator, it's natural to feel disconnected from other businesses. The cannabis industry is unique, relatively new, and evolving quickly.

BONUS SECRET:

You are not alone. You don't need to reinvent the wheel.

Cannabis can take advantage of overlaps in parallel industries, such as pharmaceuticals, nutraceuticals, food, agriculture, and postharvest. For example, cannabis and hops (*Humulus*) share an ancestor and have some similarities, including appearance and aromatic terpenes, such as myrcene and limonene. Both plants produce resinous glands and have medicinal uses. Why not take the knowledge from legacy industries or other crops such as hops and apply it to cannabis? This is especially advantageous for postharvest techniques for drying, moisture content, forced air, and drying racks. Packaging vessels, storage conditions, and shelf-life are essential variables that directly impact the health of a crop, and the profitability of your operation – especially microbial contamination. Learning from these industries and other crops help enhance the cannabis industry eliminating the trial-and-error stages others have journeyed before, and leveraging their knowledge to make a safer product.

“**Implementing sanitation practices throughout our facility allows the prevention of unnecessary challenges including *Aspergillus*. Testing during cultivation with TEMPO® and GENE-UP® shows us the risks and provides us opportunities to remediate. This keeps our product and consumers safe.**”

- AARON DUCKWORTH, VP OF R&D & QUALITY, FLURESH

Knowing the 5 secrets of *Aspergillus* will help to protect your product, profitability, and consumer health and safety throughout the lifecycle and supply chain and from indoor cultivation to the laboratory.

Best practices for preventing *Aspergillus* contamination

Aspergillus can cause contamination events or failed compliance tests requiring costly remediation. By taking several actions you can mitigate the risk while increasing product quality and consumer health. It's critical to know your environment. This allows you to implement best practices, including sanitation protocols and an ideal facility environment. In-process and environmental testing is critical prior to the required local compliance tests.

“ Cultivators can employ good cultivation practices by monitoring the environment in which the plant is grown, harvested, dried and cured. Environmental monitoring should include microbial testing of water systems, air sampling, surface contact testing as well as analyzing product for fungal contamination through the life cycle of the plant.”

- PATRICK BIRD, AOAC TECHNICAL CONSULTANT AND OWNER OF BIOTEK CONSULTING

Prevention of an infestation is key. Mold and yeast prevention are fairly simple. When a fungal spore lands on a plant, it will either grow or remain inert. Inert spores collect according to their concentration in the outside air, air exchanges, and interior airflows, and this accumulation along with active growth of organisms can be measured in several ways.

Postharvest controls include managing temperature and water-activity levels during the drying and curing process eliminating favorable conditions for mold growth. The concept of monitoring water activity is a tried-and-true method employed by the food industry, which also offers us some extreme postharvest treatment, like radiation.

To prevent infestation, there are many options available. Here are a few that have been proven effective over the years in cannabis cultivation.

To reduce risk, it's important to:



Understand what to look for before problems affect your business plan



Be prepared to pivot when federal legalization occurs



Know how regulation leads to safe consumer products setting your business up for future success



Create a collaborative and beneficial partnership with testing laboratories and the industry

Four best practices to mitigate microbial contamination:



BEST PRACTICE # 1

KNOW YOUR ENVIRONMENT

It is impossible to make your entire facility a clean room, but there are things you can do to lessen *Aspergillus*' chances of contamination. Microbial contaminants can readily grow on porous surfaces like unfinished wood, ceiling tiles, carpet, and insulation. Before setting up your operation, test the facility using swab samples for all of the above surfaces, and physical samples for things such as plant material and growing components like soil and coco coir. Understanding your environment allows you to put the checks and balances in place, avoid unexpected issues, and be proactive. This can be done in a few simple steps including:



Identifying challenge points



Understanding air quality and flow



Implementing risk analysis and HACCP



A routine environmental monitoring program

HOW TO IDENTIFY RISKS

There are many options to monitor your plants and your facility for contamination. Live cannabis plants naturally defend the constant attacks of *Aspergillus*. Postharvest, a plant cannot defend itself and becomes susceptible to *Aspergillus* creating the need to further identify risks. You don't need to be a microbiologist to recognize contamination with this process. Air sampling with spore traps can be done to provide a simple and visual tool for understanding air contamination.

More scientific solutions are available such as implementing culture plates or rapid microbiology methods to tell you the specific viable organisms in the sample. Automation and rapid options bring standardization and remove subjectivity. TEMPO® is an automated option from bioMérieux, Inc. providing simplicity, standardization, and science to help you identify and mitigate risks.

Regardless of the method, it's important to analyze the data and determine the critical control points in your facility. The data subsequently can be utilized in several ways including leveraging your facility map or floor plan to lay out the results in an effective way to see any hot spots and proactively stop future issues. bioMérieux has a suite of solutions and expertise available to help you understand your facility, your microbiome, and eliminate risks.

IMPLEMENTING RISK ANALYSIS WITH HACCP FOCUS

HACCP (Hazard Analysis and Critical Control Points) is a systematic preventive approach commonly used in the food safety industry to address biological, chemical, and physical hazards in the production processes that create risks causing the finished product to be unsafe. HACCP's intention is to determine the risks and the location of the risk to create proactive actions to reduce the known risks to a safe level. The implementation of HACCP within the cannabis industry fuels the proactive approach needed to mitigate risks including *Aspergillus* while improving quality and safety. If you are looking to create a HACCP plan, there are many resources online including guidelines by the FDA.

AIR QUALITY

When it comes to getting rid of mold when growing cannabis, an ounce of prevention is worth a pound of cure. Air purification prevents mold proliferation. Fungicides and natural mold inhibitors can only do so much to get rid of mold spores. The best approach to prevent spore spread is to use specialized air purification, such as a hospital-grade HVAC system that has HEPA filtration and UV light. Routine system maintenance, along with air quality monitoring, ensures optimal air quality.

MONITOR TEMPERATURE AND HUMIDITY

Some cannabis cultivators have used home remedies like placing a tortilla in a bag with cannabis for storage to increase moisture so the flower will not dry out. This practice along with a myriad of other techniques can introduce unwanted contaminants or residuals that lead to compliance failures and consumer safety concerns. It is best to now rely on the most current science technology to understand how to successfully grow and store cannabis crops to meet the regulation demands for clean and safe products.

Temperature and relative humidity are the top two factors in healthy crops. While there are ideal sweet spots for temperature and humidity to decrease microbial growth, for postharvest cannabis, it is still complicated since the consumer preference supports a higher temperature and relative humidity to increase moisture content in the cannabis flower. The problem is increased moisture content in flower brings increased microbial growth. It's a double-edged sword.

"A product recall for mold can jeopardize a producer's bottom line, consumers' health and the entire industry's legitimacy." – Rachele Gordon, on behalf of Boveda®

There are new advancements with commercially available humidity packs to regulate humidity in closed containers. The systems are designed to ensure constant humidity is maintained while protecting the crop. This type of technology can help decrease microbial growth on post harvest cannabis flower batches.



BEST PRACTICE # 2

IMPLEMENT SANITATION PRACTICES

Sanitation practices are essential to product quality, safety, and profitability. There are a wide range of products and options available based on your operational goals and needs. Sanitation practices include and are not limited to environmental surface treatments, harvest controls, air monitoring, material standards, and PPE (Personal Protective Equipment).

SURFACE TREATMENT

If you have ever had a slimy pink ring around your shower drain; this is a biofilm. *Aspergillus* can create biofilms and are frequently created by *A. fumigatus*, one of the most significant pathogens in chronic pulmonary aspergillosis in humans. Because microbes want to reproduce and flourish, it has a defense mechanism within the biofilm structure. There are actual electrical charges on the slime surface, making the surface more resilient to antifungal treatments. Microbes in isolation are much easier to eliminate than microbes in a biofilm. Physical disruption of the microbial network is needed by scraping and removal of the biofilm.

This is followed by chemical treatment. Chemically treating your facility is important to stop *Aspergillus* from progressing into a biofilm network.

Facility sanitation practices require chemical treatment and other volatile processes keeping your facility and instrumentation clean, while eliminating hidden contaminants. There are many elements to consider when implementing sanitation practices. A few commercially-available practices include:

- ***Routine chemical fogging or volatile treatments (ozone, chlorine dioxide)***
- ***Chemical surface sanitation in conjunction with UV light disinfection***

It's necessary to research options and confirm what is best for your operations. Treating surfaces proactively decrease your risks, increase safety, and create opportunities for growing high quality products.



POST HARVEST CONTROLS

ENVIRONMENTAL CLEANING

Handling cannabis on clean surfaces increases the possibility for a higher quality product. This simple application replicated throughout the supply chain — cultivation, harvesting, drying, curing and distribution — is essential for reducing contamination risks. This holds true in dispensaries at the point of sale, especially in instances where loose leaf options are available for purchase and include vending and weighing. Most surfaces in dispensaries are made of glass, stainless steel, or some other surface that is non-porous, and can be easily cleaned and sterilized routinely. Cultivation facilities and dispensaries can benefit from environmental swabbing for *Aspergillus*, other mold, and bacteria that impede quality, decrease profits, and pose a high risk to human health and safety. Your product quality, shelf-life, and consumer safety all benefit from non-toxic cleaning agents used to wipe surfaces; a simple step with a strong impact.

PPE

When clipping the plant or handling cannabis, have a standardized plan in place to implement the use of PPE (gloves, laboratory coats, and masks) and change them often to ensure sterilization. Having a process in place provides the understanding and guardrails for employees and visitors to flourish and not accidentally breach set protocols. When it comes to handling cannabis with tools such as trimmers, it is best practice to autoclave or chemically sterilize your trimmers after each use between crops. Purchasing trimmers that can withstand chemical and/or temperature sterilization is worth the added expense.

MATERIAL STANDARDS

It's essential to have material standards and best practices because packaging can harbor contamination. Bags and totes should be single-use only.

Cannabis packaging guidelines to know include:

- ***Oven or turkey bags can be used for fresh packing***
- ***Do not reuse bags***
- ***Sealable vacuum bags work***
- ***Sterile bags are available and are expected to become the standard over time***
- ***It is not advisable to put cannabis directly into plastic totes. If using totes, they need to be cleaned regularly. Having a one-time use bag inside the totes reduces the risk of contamination.***

PRO-TIP: Brand new totes often used in the cannabis industry are treated with pesticides and other residual contaminants that can affect your crops and contaminate, leading to consumer safety concerns. Know the origin of your totes and materials to prevent introduction of contamination to your process.

Medical grade cannabis rules:

- ▶ *Medical grade cannabis should never be placed on the ground*
- ▶ *Do not package it in unclean areas*
- ▶ *It should not be handled in rooms with carpet*
- ▶ *Collectives should only handle medicine on counters that are above waste level*
- ▶ *Diligent disinfecting of work surfaces (hydrogen peroxide, peracetic acid, sodium hypochlorite/bleach solution)*
- ▶ *Incorporate proper PPE use*
- ▶ *Implement environmental control management*
- ▶ *Avoid moisture and condensation on susceptible surfaces*



BEST PRACTICE # 3

IN-PROCESS AND ENVIRONMENTAL TESTING AND OTHER TESTING

A crop worth \$500,000 contaminated with *Aspergillus* will lead to a remediation plan of destroying the crop or repurposing to a less profitable commodity. To avoid the loss of time, money, and materials, consider these prevention tips:

Redesign your workflow within your facility after testing. Identifying 'hot spots' which can lead to improvements to the infrastructure and/or processes. Systematic organization is necessary in decreasing your chances of microbial contamination.

Partner with your compliance testing laboratory to conduct initial and routine non-compliance testing to understand the risks and provide the opportunity to mitigate the risks. Alternatively, many indoor cultivation facilities opt to bring this testing in-house. It's critical to have a test method that works well in your operations and keeps things simple. bioMérieux offers several novel solutions to support the industry needs for *Aspergillus* testing while maintaining simplicity in the process and putting science first. It's essential to utilize technology that is reliable and robust so you receive accurate results that drive the direction of other proactive practices in your laboratory.

Learn more about GENE-UP® *Aspergillus*PRO® at <https://go.biomerieux.com/us-cannabis>

Test all components used to grow the cannabis — tools, surfaces, environment, air flow. Create routine sampling and testing of the facility and plants before there is a problem. Testing can be done by partnering with your compliance testing laboratory or adding an in-house testing laboratory. By being proactive, you increase product quality and consumer safety. It is beneficial to know your challenges before you start and during the process. This reduces or eliminates the surprises when you send your products for the final compliance testing.

Expand your scope of testing helps you understand risks and work towards mitigation proactively. With all the work and effort you are putting into your plants, you want to avoid at all costs having to rework or destroy your crop. Having indicators of quality and safety with help you improve process, quality, and yields by implementing additional non-compliance testing.

Test soil and any other growing materials like coco coir before bringing it into your facility. Even if you have clean starting components, *Aspergillus* can enter the facility at any time and propagate to ultimately contaminate your product.

Test the HVAC system, all porous surfaces, and any surface cannabis comes into contact with often.

Sample the air of your indoor cultivation or laboratory to provide you essential information on what microbes you are harboring in your environment. This information is your power to be proactive and address critical control points and other risk factors creating the problem. Air sampling is generally cost effective and requires a minimal skillset to implement on-site or one can leverage the relationship with their local compliance testing laboratory. Although effective in function and cost, air sampling is less commonly utilized within the cannabis industry. Cannabis cultivation is an agriculture activity and in many agricultural activities are exempt from air sampling programs. Cannabis indoor cultivations and laboratories are not exempt from the risk for airborne contaminants. There are many air sampling devices on the market including AIR IDEAL® by bioMérieux.



<https://www.biomerieux-usa.com/industry/air-ideal>



BEST PRACTICE # 4 TAKE A PROACTIVE APPROACH

When you proactively identify where the challenges are, they can be reduced or eliminated. Being able to predict issues will save you time, mitigate the risks, improve product quality, streamline safety, and generate increased profitability.

Remediation of the root cause is essential to determine the core problem, find a solution, and implement the corrective actions to remedy the issue. Root cause analysis helps you identify and describe the problem accurately and serves as a key factor in the remediation process. This includes the determination of corrective actions and a timeline for implementation of the corrective actions. Preventing the situation from reoccurring saves time and money while building a stronger infrastructure. Root cause analysis is part of your Quality Program or Quality Manual. This is linked to any accreditations of your facility such as ISO 17025.

Consistency is key when establishing a testing routine - Being reactive breeds inconsistency costing time, labor, and profitability. It does not have to be this way. By implementing best practices and keeping up with them routinely you can continue to build your Quality Management Program to drive success.

“Cannabis companies need to think about the future of their company. To be reactive instead of proactive is the certain path to failure down the road. Becoming compliant with already existing FDA standards or becoming cGMP Certified now is the number one way to ensure your long term company success”

- KIMBERLY STUCK FOUNDER, CEO ALLAY CONSULTING LLC



Choosing a testing method

Microbiology testing is a vital indicator for product safety. There are many things to consider when building a microbiology laboratory on-site or finding a laboratory to meet your testing needs.

First, understand the risk and goals by consulting with scientific experts. There's value in scientific expertise in cannabis; it is equally important that your resources and suppliers know and understand microbiology.

Performing microbiology testing doesn't need to be challenging. In fact, it can be very simple. Know your options and the differences and have testing performed routinely. The simpler the sample prep and the process, the easier life in your laboratory will be, and the more confidence your team will have that they are following the procedure correctly.

Not all scientific solutions are created equal. Rapid microbiology solutions remove the guess work. Select a rapid microbiology method that meets local state regulations; to be a real solution, the regulatory requirements must be achieved. It's critical the solution also embraces robust and reliable science. Scientific credibility is proven by independent laboratory testing and approval via organizations like AOAC. Select a company with a rich history in microbiology and experience with diverse and difficult matrices and this will take you further, faster.

Consumer safety microbiology testing is not new. The cannabis matrix is easily adopted into cannabis microbiological testing without reinventing the wheel. There are companies with vast expertise in microbiology, diverse matrices, and across multiple disciplines to ease the learning curve. One of these companies is bioMérieux. Leveraging their experience in industrial microbiology, bioMérieux enhances the cannabis industry with their comprehensive offering of cannabis-validated microbial testing solutions. As the worldwide leader in microbiology and over 55 years' experience, bioMérieux partners with indoor cultivators, vertically integrated operations, and cannabis compliance laboratories to provide increased product safety and human health with their robust and reliable cannabis-validated test solutions and consultative partnership.

Strong partnerships are essential. Knowing you have a cannabis microbiology partners that will walk hand-in-hand with you not only in setting up, training, and supporting validations, it's essential they are an extension of your operations and will be there to support when things don't go as planned. When working with biological organisms, unique situations will arise. So, it's vital to select a partner rather than just a supplier.

Considerations of selecting a testing method

Regulations anchor microbiology testing. With variation state-by-state, it is important to know and understand the regulations while navigating a solution for cannabis microbiology testing. There's benefit to know the type of testing needed and the specifications surrounding the test. Types of testing may include, and are not limited to: *Aspergillus*, *Salmonella*, STECs, and yeast & mold. *Aspergillus* testing requirements are expanding as new states come online with cannabis regulation. Current states with either or both medical or adult-use programs are revising regulations to include *Aspergillus*. When selecting a method consider the following 5 factors:

1. *Scientific Integrity - AOAC INTERNATIONAL Approval & Scientific Validation*
2. *Testing Simplicity*
3. *Partnership and Support*
4. *Reputation*
5. *Scope of Business*

It's essential to dive deeper into each factor.

Scientific Integrity - AOAC Certification & Scientific Validation

- ▶ *Not all scientific solutions are created equal.
Rapid microbiology solutions remove the guess work*
- ▶ *Select a rapid microbiology method that meets local regulations*
- ▶ *To be a solution, the regulatory requirements must be achieved*
- ▶ *Critical the solution embraces robust and reliable science*
- ▶ *Scientific credibility is proven by independent laboratory testing and approval via AOAC*

Combine this with a company with a rich history in microbiology and experience with diverse and difficult matrices and this will take you further, faster. Most *Aspergillus* regulations require zero tolerance which equates to less than 1 CFU/g. The method selected needs to reach this specification to meet your state regulations and ensuring product and consumer safety.

Testing Simplicity

Cannabis microbiology is overwhelming enough; why make things harder with tests that require many steps or robots? The method you select will be performed day in and day out in and needs to be very simple and fit your operations. Selecting solutions that are so simple that you don't need to be a microbiologist to perform them, and they provide you with confidence in your testing results is essential.

It is **NOT** the optimal solution if:

- ✘ *You need to spend thousands of dollars (and bench space) on a robot*
- ✘ *The kits and materials to perform the tests don't come pre-weighed or pre-measured ready for use*
- ✘ *There are more than a few simple steps*
- ✘ *Aspergillus testing requires a DNA extraction or purification manual process*
- ✘ *If you are required to send off data to get results back or results require interpretation*
- ✘ *The Aspergillus result does not provide you upfront speciation*
- ✘ *Enrichment is not needed*
- ✘ *You need to add additional steps for dead (free) DNA*
- ✘ *There's the requirement for different sample preparations for the diversity in cannabis matrices (products)*

Partnership and Support

Strong partnerships are essential. Knowing you have cannabis microbiology partners that will walk hand-in-hand with you setting up, training, and supporting validations; it's essential they are an extension of your operations and will be there to support when things don't go as planned.



Reputation

Find a well-established partner with expertise in microbiology and experience across multiple industries such as food, pharmaceuticals, nutraceuticals, and cannabis with an emphasis on protecting human health and public safety such as bioMérieux. Their reputation will help protect yours.

Scope of Business

bioMérieux provides you scientific integrity and AOAC INTERNATIONAL approvals, simple sample prep and workflow, anchoring on their vast knowledge in microbiology in many industries to help you navigate the difficult matrices in cannabis. bioMérieux's knowledge and commitment to public health and safety will help you meet your local regulations and goals with an anchor in science.

To simplify your microbiology process with robust and reliable science with a trusted partner learn more at <https://go.biomerieux.com/us-cannabis>



Microbiology Consultant: When to hire and what to consider

When you hire a consultant or additional resources, it's commonplace to establish the scope of work and provide payment upfront. There are many elements to consider in hiring a support network. This starts with understanding your needs and goals to set a strategy to reach success. This requires either a great laboratory director or a great consultant. This will create a path for success and ensure you do it wrong the first time.

Setting your laboratory up for success at the beginning requires understanding the big picture and then moving to the details. The details require someone with experience navigating not only laboratory specifics, but also regulating body specifics, including the knowledge of what is to come. State regulations may change overnight and are in effect immediately. Being able to predict changes and pivot immediately requires an experienced individual. Understanding how future federal regulations may affect current regulations is just as important as current regulations.

Planning starts from a proper laboratory building that is conducive to cannabis testing and not contaminated with microbes, pesticides, or other contaminants. From there setting up the floorplan and workflow is crucial. All of this is before even hiring laboratory personnel. Capital purchases need to be planned early on as well. Getting the backbone of your laboratory wrong will haunt you moving forward since many tasks will not have optimal outcomes due to planning, improper instrumentation or equipment, and contamination. Getting the proper help early on will save a lot of headaches and reduce wasted time. In the long run, you will save money by not creating costly mistakes.

There is always the ethical, right way to do science. Sometimes inexperienced laboratories do not understand the details and are unaware of wrongdoings. This is where an experienced consultant can help set up the laboratory the right way at the beginning. Some laboratories have been able to get away with unethical practices which can put consumer safety at risk, but infractions will surface at some point. Running proper controls, confirming failures, performing aseptic technique, and not contaminating samples in the laboratory are all necessary to run a proper microbiology operation.

Having the proper laboratory personnel is the key factor in a successful laboratory. The hiring process can be complicated, especially in a newly regulated industry like cannabis where there is a stigma, and many qualified scientists are not ready to make the leap into the industry. Because of this, there are a lot of 'con artists' in the industry and these people can destroy a company, leading the laboratory in the wrong direction, with dishonesty about their scientific background, cutting corners, and even fabrication of data. A good consultant can help in the hiring process and even be involved in interviews to vet the candidates. The role of the consultant is to 'Train the Trainer' so that when the consultant's job is complete, the laboratory can function independently with confidence and ease. Even after getting set up, it is recommended to have a consultant on hand for situational issues and questions, either on a retainer or an hourly basis.

There's a lot to consider. You are not alone when dealing with *Aspergillus* in your cannabis operation.

The challenges with *Aspergillus* are common throughout the cannabis industry. Navigating *Aspergillus* doesn't have to be daunting. When you implement the above best practices and partner with trusted microbiology experts, together you expose the secrets of *Aspergillus*, disarming its destruction, while increasing product quality and safety.





ABOUT THE AUTHORS

Renee Engle-Goodner



Renee Engle-Goodner has possessed a deep, lifelong passion for science and innovation. She earned a Genetics BS from UC Davis. Renee's research focused on forensic entomology. She received her Genetics MS from UW-Madison. Renee worked for AgroFresh as a Laboratory Manager, EH&S Site Manager and Senior Biologist. She has worked for Delicato Family Wines as their Analytical Laboratory Manager. Renee was also the Chief Scientific Officer at the first non-legacy laboratory validated under the strict new enforcement regulated by the Bureau of Cannabis Control. REG Science, LLC is Renee's regulatory science consulting company where she is the Principal Consultant. Renee is a serious advocate for safe and clean cannabis products in this budding, evolving industry.

Maria McIntyre



Maria McIntyre, a trailblazer in Cannabis Microbiology who has a lifelong enthusiasm for human health and public safety reflected in science, education and innovation. Having the distinctive and dichotic education in both biology and chemistry led her to R&D roles within food science, pharmaceuticals, regulatory compliance, and microbiology. She utilizes her background and experience today at bioMérieux as Strategic Operations Business Manager: Cannabis + Hemp Microbiology to improve product safety and human health in the cannabis industry.

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