May 4, 2025

Chairs Senator Hickman and Representative Supica
Veterans and Legal Affairs Committee
State of Maine

Dear Chairs Senator Hickman and Representative Supica,
As industry leaders in cannabis and pathogen genomics, we have spent decades working with quantitative polymerase chain reaction (qPCR) and culture-based methods for the detection of microorganisms. We are experts in the field with over 40 patents related to PCR and DNA sequencing based methods for detecting microorganisms. Kevin McKernan, Chief Scientific Officer at Medicinal Genomics Corporation (MGC) managed the Research and Development team for the Human Genome Project at the Whitehead Institute of MIT. He has over 63,391 citations related to his work in this field. Our scientists recommend the microbial testing specifications that will ensure that medical and adult use cannabis plant material and manufactured products are safe for consumers. Due to concerns for public health, the Veterans and Legal Affairs Committee should consider modifying and or combining relevant sections of the testing bills (LD 1847 - An Act to Institute Testing and Tracking of Medical Use Cannabis and Cannabis Products Similar to Adult Use Cannabis and Cannabis Products, Dedicate a Portion of the Adult Use Cannabis Sales and Excise Tax to Medical Use Cannabis Programs and Create a Study Group [1]; LD 104 - An Act to Protect the Health of Medical Cannabis Patients and Streamline the Mandatory Testing of Cannabis [2]; and LD 1620 - An Act to Amend the Laws Regulating the Testing of Adult Use Cannabis and Adult Use Cannabis Products [3]), to detect specific microbial human pathogens that reflect ongoing efforts at AOAC International, ASTM International, the United States Pharmacopeia (USP), the Centers of Disease Control and Prevention (CDC), and the United States Food and Drug Administration (FDA) that are consistent with our findings at MGC.

The presence of microorganisms is common on plants, such as cannabis. One must be able to differentiate between harmless and/or beneficial microbes (bacteria, yeasts, and fungi) ubiquitous in nature and those that are human pathogens that have contaminated the cannabis plant material and/or manufactured products. Examples of human pathogens that have been detected in cannabis are Shiga toxin producing *E. coli* (STEC), *Salmonella* species, *Aspergillus flavus, A. fumigatus*, *A. niger*, and *A. terreus* [4-32].

Current required tests for microbial contamination in states that have both medical and adult use cannabis programs vary among the states. Some states require different combinations of some of the following tests: total viable aerobic bacteria (TAVB), total yeast and mold (TYM), total Enterobacteriaceae (TE), and total coliform (TC), and the six human pathogens listed above with various action levels for each test and each cannabis product type. On the other hand, other

states, such as California, Montana, and Vermont only require specific tests for detecting the human pathogens, such as STEC, *Salmonella* spp., *Aspergillus fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* for inhalable products and STEC & *Salmonella* spp. for non-inhalable products. **NOTE:** Total count tests have action levels as colony forming units (cfu/g), which is the number of colonies that grow on the surface of an agar medium plate. Specific pathogen tests usually have an action level of "<1 CFU/gram".

In LD 1847 Sec. 7. 22 MRSA §2430-P is enacted to read:

1. Scope of mandatory testing.

C. **Dangerous yeasts, molds and mildew** as specified in rules adopted by the department;

D. **Harmful microbes**, including, but not limited to, Escherichia coli and salmonella;

In LD 104 Methods for Microbial testing Sec. A-27. 22 MRSA §2429-E is enacted to read:

1. Scope of mandatory testing generally.

C. **Dangerous molds and mildew**, including mycotoxins, as applicable;

D. **Harmful microbes, including, but not limited to, Escherichia coli and Salmonella**;

In LD 1620, Test sampling size and Microbial tests are required for each sample type - Sec. 1. 28-B MRSA §601, as amended by PL 2023, c. 679, Pt. B, §112, is further 3 amended to read: §601. Testing program established

…The rules must establish a **testing limit for total yeast and mold contamination in adult use cannabis and adult use cannabis products of 100,000 colony-forming units per gram** and may require other microbial testing only for microbes injurious to health, as determined by the office, including, but not limited to, Escherichia coli, salmonella and coliform bacteria. Rules adopted pursuant to this subchapter are routine technical rules as 20 defined in Title 5, chapter 375, subchapter 2-A.

Moreover in Section 6.10 - Microbiological Impurities, Table 6.10-A. Limits for Microbiological Contaminants in CFU/g from the STATE OF MAINE RULES FOR THE CERTIFICATION OF CANNABIS TESTING FACILITIES CODE OF MAINE RULES CHAPTER 5 (unmarked version) [33] states:

Cannabis Material	TVAB	TYM	TE	TC	E. coli (STEC)	Sal
Plant Material/Cannabis Products	10+5	10+4	10+3	10+3	<1/g	<1/g
CO2/Solvent-Based Concentrates	10+4	10+3	10+2	10+2	<1/g	<1/g

Based on analytical limits based on American Herbal Pharmacopoeia, Revision 2014.

Our first recommendation is requiring testing to detect the human pathogens that have been associated with cannabis use (the six pathogens listed previously) for flower and processed products that can be administered through the inhalation route. The United States Pharmacopeia (USP) stated that "Many states with legalized cannabis markets now require that all cannabis

goods intended for consumption by inhalation be tested for the four pathogenic *Aspergillus* species (*A. flavus, A. fumigatus, A. niger,* and *A. terreus*). When inhaled, all four of these species are known to cause a variety of immune lung disorders, ranging from asthma, allergic bronchopulmonary aspergillosis, and hypersensitivity pneumonitis to invasive and life-threatening systemic fungal infections in immunocompromised hosts." [34]

The number of states and territories that require microbial testing rules for inhaled cannabis products (flower, pre-rolls, vape pens, *etc*) was 26 in 2019 [35] and 42 in 2024 [36]. A comparative analysis of the required microbial testing rules for all jurisdictions with legal cannabis programs in 2019 and in 2024 showed that the percentage of states and territory that require the detection of the pathogens listed above has increased during this 5 year period (see the following table).

Microorganism (2019)	# (%)	Microorganism (2024)	# (%)	% Increase over 5 years
Salmonella species	22 (85%)	*Salmonella* species	40 (98%)	**13%**
STEC	4 (15%)	STEC	18 (43%)	**28%**
4 *Aspergillus* species	8 (31%)	4 *Aspergillus* species	24 (57%)	**26%**

Since other states and territories are in the process of modifying their microbial testing rules and new states & territories will legalize cannabis in the future, we predict that the percentage of jurisdictions requiring the detection of microbial pathogens for inhaled products will continue to increase.

Our second recommendation is that total microbial count tests ("indicator tests"), such as TVAB, TYM, TE, and TC must not be required, because indicator tests do not directly test for pathogens. Moreover, while microbial and fungal limits are not typically reported as "pass/fail," the MNOCM has established acceptable limits of detection. Total count tests do not provide pathogen-specific data relevant to cannabis safety. Relying on broad microbial counts provides no clear indication of human health risk.

Rationale for Second Recommendation

1. **Lack of Pathogen-Specific Data**

According to the American Herbal Pharmacopoeia's 2014 Monograph on Cannabis Inflorescence [37], total microbial count tests **should not** be used as a basis to fail cannabis samples simply for exceeding action levels. These tests, which include TVAB, TYM, TE, and TC do not differentiate between harmful and benign microorganisms. Therefore, a total count test result **provides no** information about the presence of human pathogens. Moreover, there are 35 microbiological pesticides that have been approved for cannabis cultivation by one or more states (MGC dataset). The primary ingredient in these microbiological pesticides is either a

beneficial bacterial or fungal strain. These beneficial microorganisms prevent pest infection (bacterial, fungal, insect, and/or nematode cannabis pathogens) that could lead to reduction of cannabinoid yield or total crop loss. Required total count tests cause cultivators to use toxic chemical pesticides instead of harmless microbiological agents.

2. **No Link Between Total Count and Disease**
There are no peer-reviewed studies demonstrating that specific thresholds of total microbial counts (TVAB, TYM, TE, or TC) are correlated with human disease. Without such research, it is scientifically unjustified to rely on these counts as criteria for failing cannabis samples.

3. **No Clinical Evidence from Cannabis Use**
To date, no clinical case studies have shown that total microbial counts (TVAB, TYM, TE, or TC) on cannabis lead to human illness. The lack of such evidence further questions the relevance of these tests for ensuring public health safety.

4. **Failure to Satisfy Koch's Postulates**
Koch's Postulates, the gold standard for establishing a microorganism's role in causing disease, cannot be fulfilled by total count tests. These tests do not isolate or identify specific pathogens, but instead measure a broad and often harmless community of microorganisms. Without isolating disease-causing species, total counts cannot accurately assess the risk of human illness.

Therefore, the following modifications should be made to the above - Table 6.10-A. Limits for Microbiological Contaminants in CFU/g
1. For MICROBIOLOGICAL TESTING OF DRIED RAW CANNABIS and INFUSED PRODUCTS FOR INHALATION

	Standard
Shiga toxin producing strains of *Escherichia coli* and *Salmonella* species	< 1 CFU/g
Aspergillus flavus	< 1 CFU/g
Aspergillus fumigatus	< 1 CFU/g
Aspergillus niger	< 1 CFU/g

Aspergillus terreus	< 1 CFU/g

NOTE: The action levels for all tests listed in the table above should be "<1 CFU/10 g" to allow for a sample size recommendation that follows.

2. For MICROBIOLOGICAL TESTING OF INFUSED EDIBLES

	Standard
Shiga toxin producing strains of *Escherichia coli*	< 1 CFU/g
Salmonella species	< 1 CFU/g
Listeria monocytogenes	< 1 CFU/g

3. For MICROBIOLOGICAL TESTING OF INFUSED NON-EDIBLES

	Standard
Candida albicans	< 1 CFU/g
Pseudomonas aeruginosa	< 1 CFU/g
Staphylococcus aureus	< 1 CFU/g

Our third recommendation concerns the allowable methods to detect these recommended 10 human pathogens for the different sample types, which should be molecular detection. In light of advancements in laboratory technology and the critical need for accurate and timely pathogen detection, MGC recommends that the Maine Office of Cannabis Policy allow molecular testing

methods, such as qPCR and other DNA-based assays, as validated technologies for specific cannabis pathogen testing.

Molecular methods offer significant advantages over traditional agar plating, which includes greater specificity & sensitivity for detecting the human pathogenic species of *Aspergillus, Salmonella*, and Shiga-toxin producing *E. coli* (STEC), *Candida, Pseudomonas, and Staphylococcus*. These methods can provide results in hours rather than days, enhancing safety by enabling faster decision-making in product release, and reducing the risk of contaminated products reaching consumers. The adoption of molecular methods will align Maine's cannabis testing regulations with those in other highly regulated industries, such as food and pharmaceuticals, which already leverage these tools to ensure product safety. By allowing for molecular testing, Maine can strengthen its public health protections, support innovation in its testing labs, and streamline the regulatory compliance process for cannabis producers and testing facilities.

Most importantly, there are multiple AOAC certified Performance Tested Methods (PTMs) using cannabis as a sample type that are being used by licensed cannabis labs throughout the world. These PTMs were developed by the AOAC Cannabis Analytical Science Program (CASP), which is a forum where the science of cannabis analysis can be discussed and cannabis standards and methods developed. To date, AOAC has released three (3) Standard Method Performance Requirements (SMPRs) for the six human pathogens that we have recommended for testing (see #1-3 below).

1. Detection of *Aspergillus* in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2019/10/SMPR-2019_001.pdf
2. Detection of *Salmonella* species in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2020/07/SMPR-2020_002.pdf
3. Detection of Shiga toxin-producing *Escherichia coli* in Cannabis and Cannabis Products https://www.aoac.org/wp-content/uploads/2021/02/SMPR-2020_012.pdf

NOTE: A SMPR for Detection of *Listeria monocytogenes* in Cannabis Edible Products will be approved in 2025.

Medicinal Genomics is a member of **AOAC's CASP Microbial Contaminants Working Group**. The goal and objectives of this working group are to:

- Develop Standard Method Performance Requirements (SMPR) for cannabis and hemp
- Extend a Call for Methods for each of the completed SMPRs
- Empanel an Expert Review Panel to review candidate methods
- Deliver consensus-based validated Performance Test Methods (PTMs) & Final Action Official Methods for the cannabis industry

Medicinal Genomics has a single AOAC Certified **qPCR** PTM for the detection of the 4 pathogenic *Aspergillus* species in one test and has a single AOAC Certified **qPCR** PTM for the detection of *Salmonella* spp. & STEC in one test. The sample types for the 4 *Aspergillus* species

test are flower, infused products, oils & concentrates, and hemp. Moreover, the sample types for the Sal/STEC test are flowers, oils, chocolates, and hemp. Each of these two **multiplex qPCR assays** were validated by an independent 3rd party cannabis testing laboratory using the various cannabis sample types.

There are several **major disadvantages** of using plating methods to detect specific bacterial and fungal pathogens:

- Cannabinoids, which can represent up to 30% of a cannabis flower's weight, have been shown to have antibiotic activity. Antibiotics inhibit the growth of bacteria. *Salmonella* & STEC bacteria are very sensitive to antibiotics, which may lead to a false negative result using a plating system *vs.* a positive result using a qPCR method. [38-39]
- The USP stated "Detection of pathogenic *Aspergillus* species using culture based methods is very difficult, requiring a highly trained and experienced mycologist to correctly identify these pathogens by colony appearance and morphology, as there are many nonpathogenic species of *Aspergillus* that may be indistinguishable from those that are pathogenic [34].
- Agar plating methods cannot detect bacterial and fungal endophytes [40-41] that live a part or all of their life cycle **inside** a plant. Examples of endophytes are the *Aspergillus* pathogens. Methods to break open the plant cells to access these endophytes for plating methods also lyses these bacterial and mold cells (killing these cells in the process). Therefore, these endophytes will never form colonies, which will lead to a false negative result using a plating system *vs.* a positive result using a qPCR method.
- Selective media for mold plating methods, such as Dichloran Rose-Bengal Chloramphenicol (DRBC) reduces mold growth; especially *Aspergillus* by 5-fold. This may lead to a false negative result for this human pathogen. In other words, although DRBC medium is typically used to reduce bacteria; it comes at the cost of missing 5 fold more yeast and molds than Potato Dextrose Agar (PDA) + Chloramphenicol or molecular methods. These observations were derived from study results of the AOAC emergency response validation [42].

Therefore the allowable methods …"using an AOAC-approved technology using appropriate aseptic techniques." quoted above should be modified to read:
A registered independent laboratory must use:
An AOAC Certified Performance Tested Method (PTM) that has an enrichment step with a minimum of sixteen hours (16 hrs) of incubation.

Our fourth recommendation is to increase the sample testing size, which is not covered in the regulations. As cannabis prices fall, a 10-gram test amount may become necessary to address sampling challenges. If the maximum batch size for taking samples for subsequent compliance and/or retention testing is 11 kgs (~22.2 lbs), and a lab currently tests 1 gram from a 11-kg batch (1 gram from 11,000 grams), this test sample size increases the risk of sample bias. Contaminants like bacteria, fungi, or toxins in a sample are often not evenly distributed throughout a batch test sample. In a 1-gram sample, there's a higher likelihood that no pathogen is present in the small portion tested, even if it exists elsewhere in the batch. Therefore, MGC suggests larger sample testing size (10 or 25 grams) to enhance one's probability of

capturing a more representative portion of the entire batch, reducing the chance of missing contaminated areas.

Our fifth recommendation is:
Implement Species-Specific Testing in Phases: Transitioning to species-specific pathogen testing should follow a phased approach to ensure accuracy, minimize disruption to the cannabis industry, and allow sufficient time for assay development and validation by method developers. These pathogen recommendations are grounded in clinical literature that highlights the potential harm posed by certain cannabis-associated microbes. Prevalence data has been sourced from Simon Fraser University (British Columbia, Canada) and Kannapedia.net, which catalog over 1,000 microbiomes of bacterial, fungal, and viral DNA found on cannabis plants across the U.S. This data helps identify and prioritize the most relevant pathogens for cannabis safety, which supports the need for a targeted testing approach.

This phased strategy will enable Maine to adopt pathogen testing protocols that are more clinically relevant, focused on consumer safety, and aligned with best practices from other states. Species-specific testing truly protects consumers by differentiating between thousands of non-harmful fungi and molds that pose no risk. California, Montana, Vermont, and 22 other US jurisdictions have already adopted this modern approach, which mirrors the protocols used in hospitals to rapidly diagnose multiple pathogens using extensive PCR-based platforms for gastrointestinal and respiratory diseases. By adopting this methodology, Maine can ensure a more accurate and safety-focused testing regime

Phase 2 - Future Considerations - The following pathogens have been found on cannabis and known to cause clinical harm.

1. *Fusarium falciforme* - Kannapedia.net (https://kannapedia.net/) and References [43-48]; Fusariosis, Skin Infections, Pulmonary Infections, Disseminated Infections, mycotoxins - References [43-44. 49-54]
2. *Fusarium proliferatum* - Kannapedia.net, References [43-48]; Fusariosis, Keratomycosis, Sinusitis, Onychomycosis, Pulmonary Infections, Systemic Infections - References [43-44. 49-54]
3. *Fusarium solani* - Kannapedia.net, References [43-48, 55]; Keratitis, sinusitis, endophthalmitis, onychomycosis, cutaneous infections, mycetoma and arthritis, organ membrane disruption - References [43-44. 49-54]
4. *Fusarium oxysporum* - Kannapedia.net, References [43-48, 55]; Keratitis & onychomycosis in both immunocompetent and immunocompromised - References 43-44. 49-54]
5. *Mucor circinelloides* - Reference [55]; Pulmonary, Cutaneous, Rhinocerebral, Gastrointestinal & Disseminated Mucormycosis - References [56-57]
6. *Mucor racemosus* - References [55]; Pulmonary, Cutaneous, Rhinocerebral, Gastrointestinal & Disseminated Mucormycosis References 56-57]
7. *Penicillium citrinum* - Kannapedi.net, References [43, 52-53, 55]; Hypersensitivity Pneumonitis, mycotoxins, Severe Asthma with fungal sensitization, Occupational Lung disease, mycotoxins, particularly citrinin. Citrinin is a nephrotoxic compound, meaning it can damage the kidneys when ingested. Reference [43-44, 48, 54, 56, 58]

8. *Penicillium expansum* - Kannapedia.net, References [43, 53, 55]; Mycotoxins, particularly patulin, which is harmful if ingested. Patulin is known to cause a variety of adverse health effects, including nausea, gastrointestinal disturbances, and immune suppression. References [43-44, 54, 56]
9. *Penicillium marneffei* - Kannapedia.net, References [42, 52]; Skin lesions, fungemia, pulmonary lesions, anemia. Typically impacts individuals with HIV, hematological malignancies, and immunosuppressive agents. It is the only species in the Penicillium genus known to cause systemic infections in humans - References [43-44, 54, 56, 58]
10. *Candida albicans* - Kannapedia.net; Oropharyngeal candidiasis (oral thrush): Common in those with HIV/AIDS, Vulvovaginal candidiasis (vaginal thrush), Candidemia/disseminated infections, Pneumonia, Meningitis, paronychia, onychomycosis, endocarditis, eye infection, and intertriginous candidiasis - Reference [59]

I thank you for your time and consideration. If you have any questions, please feel free to contact me.

Respectfully,

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Director of Regulatory Affairs
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2. LD 104 - An Act to Protect the Health of Medical Cannabis Patients and Streamline the Mandatory Testing of Cannabis https://legislature.maine.gov/backend/App/services/getDocument.aspx?documentId=107979
3. LD 1620 - An Act to Amend the Laws Regulating the Testing of Adult Use Cannabis and Adult Use Cannabis Products https://legislature.maine.gov/backend/App/services/getDocument.aspx?documentId=115353
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NOTE: This written written public testimony makes recommendations that impact LD 1847, LD 104, and LD 1620. I will also like to give an virtual via zoom - an oral testimony.

I would appreciate that you send me a zoom link for today's committee meeting, which starts at 9:30 am EDT.

I thank you for your time and consideration.
Respectfully
Dr. Sherman Hom