



MEMORANDUM

TO: Chair and Members of the Board DATE: March 22, 2021
FROM: Jane P. Sawyer
Regulations Specialist RE: Land & Seas Laboratory lic.
23634

Land & Seas Laboratory, a marijuana testing facility, is requesting a change to its MJ-06. The change(s) is:

2) The method of testing microbials will remain the same (polymerase chain reaction or PCR), but the kit used will be Medicinal Genomics with their method of extraction and reagents. We request to keep BioRad kits and method still available as a back-up, as they were also approved by DEC. Due to COVID, items related to PCR testing are very difficult to procure because they are used for the COVID testing. Medicinal Genomics' PCR would be our primary method of testing, as this is easier to procure because they are cannabis specific. Having both Medicinal Genomics and Bio-Rad as a back-up would allow us some latitude if items are difficult to procure or shipping is delayed. THIS IS NOT A CHANGE TO OUR OPERATING PLAN. This does change the kit manufacturer name in the SUPPLEMENTAL FORM to the MJ-06. Attached is the supplemental form with the addition of the Medicinal Genomics kits stated as the primary supplier and method of testing.

This change has been reviewed and approved by our partner DEC- EHL, therefore, AMCO director has temporarily approved it. Attached is the MJ-15 application.





Alaska Marijuana Control Board

Form MJ-15: Operating Plan Change

What is this form?

This operating plan change form is required for all marijuana establishment licensees seeking to change a licensed marijuana establishment's existing operating plan, as required by 3 AAC 306.100. With this form, a licensee may request changes to as much or as little as desired of Form MJ-01 and/or the corresponding operating plan supplemental for the establishment's license type.

The required \$250 change fee may be made by check, cashier's check, or money order.

Please complete and submit with this form the pages of Form MJ-01 and/or the corresponding operating plan supplemental that contain sections that you are requesting to change. **All fields must be completed of any page for which you are requesting changes** – upon board approval, the submitted pages will replace those currently on file. If your current, approved operating plan is on the original version of the forms, you may be required to complete and submit the new operating plan forms in their entirety.

The form(s) that I am requesting board approval to change is:

- Form MJ-01: Marijuana Establishment Operating Plan
- Form MJ-03: Retail Marijuana Store Operating Plan Supplemental
- Form MJ-04: Marijuana Cultivation Facility Operating Plan Supplemental
- Form MJ-05: Marijuana Product Manufacturing Facility Operating Plan Supplemental
- Form MJ-06: Marijuana Testing Facility Operating Plan Supplemental

This form must be completed and submitted to AMCO's main office prior to changing existing operations. The licensed establishment's operations may not be altered unless and until the director has given temporary approval or the Marijuana Control Board (MCB) has given final approval of the changes. Please note that licensees seeking to change operating plans for multiple licenses must submit a separate completed copy of this form for each license.

Section 1 – Establishment Information

Enter information for the business seeking to be licensed, as identified on the license application.

Licensee:	Land & Seas Laboratory, LLC	MJ License #:	6a-23634		
License Type:	Testing Facility				
Doing Business As:	Land & Seas Laboratory				
Premises Address:	3516 W. Coghlan Circle #3				
City:	Wasilla	State:	Alaska	ZIP:	99623



JAN 11 2021



Form MJ-15: Operating Plan Change

Section 2 – Summary of Changes

Provide a summary of the changes for which you are requesting approval.

- 1) Please change the phone number associated to our account in METRC to the business phone, rather than my personal cell phone, which is what people now use to call the business due to having it listed as our contact information from AMCO. The number should be (907) 357-9800. Thank you!
- 2) The method of testing microbials will remain the same (polymerase chain reaction or PCR), but the kit used will be Medicinal Genomics with their method of extraction and reagents. We request to keep BioRad kits and method still available as a back-up, as they were also approved by DEC. Due to COVID, items related to PCR testing are very difficult to procure because they are used for the COVID testing. Medicinal Genomics' PCR would be our primary method of testing, as this is easier to procure because they are cannabis specific. Having both Medicinal Genomics and Bio-Rad as a back-up would allow us some latitude if items are difficult to procure or shipping is delayed. THIS IS NOT A CHANGE TO OUR OPERATING PLAN. This does change the kit manufacturer name in the SUPPLEMENTAL FORM to the MJ-06. Attached is the supplemental form with the addition of the Medicinal Genomics kits stated as the primary supplier and method of testing.

Section 3 – Declarations

Read each statement below, and then sign your initials in the corresponding box to the right:

Initials

The proposed changes conform to all applicable public health, fire, and safety laws.



I understand that any temporary approval granted by the director is pending a final decision by the MCB; therefore, any investment I make, based upon temporary approval, is at my own risk.



As a marijuana establishment licensee, I declare under penalty of unsworn falsification that this form, including all accompanying schedules and statements, is true, correct, and complete.

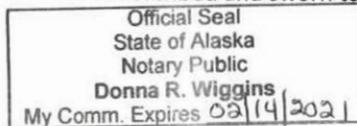
[Signature]
Signature of licensee

JESSICA ALEXANDER
Printed name of licensee

Donna R. Wiggins
Notary Public in and for the State of Alaska.

My commission expires: 02/14/2021

Subscribed and sworn to before me this 8th day of January, 2021.



AMCO Director Review for Temporary Approval Pending Final MCB Decision:

Approved Disapproved

Glen Klinkhart 1/13/2021

Printed name of Director [Signature] Date

Signature of Director [Signature]

Director Comments: [Blank Box]



Alaska Marijuana Control Board Operating Plan Supplemental Form MJ-06: Marijuana Testing Facility

What is this form?

This operating plan supplemental form is required for all applicants seeking a marijuana testing facility license and must accompany **Form MJ-01: Marijuana Establishment Operating Plan**, per 3 AAC 306.020(b)(11). Applicants should review **Chapter 306: Article 6** of the **Alaska Administrative Code**. This form will be used to document how an applicant intends to meet the requirements of the statutes and regulations.

If your business has a formal operating plan, you may include a copy of that operating plan with your application, but all fields of this form must still be completed per 3 AAC 306.020 and 3 AAC 306.615(2).

What additional information is required for cultivation facilities?

Applicants must identify how the proposed establishment will comply with applicable regulations regarding the following:

- Prohibitions
- Employee qualification and training
- Testing practices and procedures
- Reporting and records retention
- Waste Disposal

This form must be completed and submitted to AMCO’s main office before any new or transfer application for a marijuana testing facility license will be considered complete.

Section 1 – Establishment Information

Enter information for the business seeking to be licensed, as identified on the license application.

Licensee:	Land & Seas Laboratory, LLC	MJ License #:	6a-23634		
License Type:	Testing Facility				
Doing Business As:	Land & Seas Laboratory				
Premises Address:	3516 W. Coghlan Circle #3				
City:	Wasilla	State:	Alaska	ZIP:	99623

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JAN 11 2021



Section 2 – Overview of Operations

2.1. Provide an overview of your proposed facility’s operations. Include information regarding the intake and flow of marijuana and marijuana product at your premises and reporting of test results:

Land & Seas Laboratory will accept numerous agricultural sample types for safety testing, to include cannabis, hemp and hemp products, seafood, dairy, poultry, and produce. All samples will arrive through the front door of the customer entrance and go through a check-in process at the front desk under video surveillance. Samples of cannabis will be passed through an 18"x18" sample one-way window and diverted to an AMCO weigh-in process before being logged into the METRC system. Cannabis samples will be processed for any number of state-required or optional tests as described below. Results will be provided in real time on each customer's individual portal and finally in electronic reports that will be emailed and are accessible through a customer's portal, which houses all current and previous test results and invoices for each cultivator/producer/manufacturer. All chemistry results for cannabis flower will be reported in dry weight per AMCO regulation.

Section 3 – Prohibitions

Review the requirements under 3 AAC 306.610.

3.1. I certify that the marijuana testing facility will not:

Initials

- a. sell, deliver, distribute, or transfer any marijuana or marijuana product to a consumer, with or without compensation; or
- b. allow any person, including a licensee, employee, or agent, to consume marijuana or marijuana product on the licensed premises.

Section 4 – Employee Qualification and Training

Review the requirements under 3 AAC 306.625 and 3 AAC 306.630.

4.1. Name the facility’s scientific director and describe how she/he meets the qualifications set forth in 3 AAC 306.630(b):

Jessica Alexander, AAS, BAAS, MPAS, MSCRM
 Educational background:
 –Associate’s degree in Allied Health Science from Austin Community College
 –Bachelor’s degree in Allied Health Science with a minor in Chemistry from St. Edward’s University in Austin, Texas
 –Master’s degree in Physician Assistant Studies from The University of North Texas Health Science Center in Fort Worth, Texas
 –Master’s degree in Clinical Research Management (Pharmaceutical Research) from the School of Biomedical Sciences at the University of North Texas Health Science Center in Fort Worth, Texas
 –Additionally, all coursework was completed for a PhD in Molecular Cell Biology & Genetics and research was initiated, but the Department of Defense could not continue funding thesis/research on mitigation of nitric oxide species in blast injuries of tourniqueted limbs due to budget cuts associated with 9-11. Participated in graduate school research analyzing frozen porcine tissue samples collected during cardiac bypass surgery and another research project to analyze tissue samples from decubitus ulcers for angiogenic growth factor levels after pulse-pressured oxygen therapy.

Key qualifiers:
 – Current laboratory director for 2 ISO accredited laboratories-- licensed marijuana testing facility (The New Frontier Research) and food safety testing laboratory (Frontier Fare Testing) with 2 1/2 years of experience in position.
 –Previous laboratory director in the state of Alaska for 2 medical laboratories with success in management of processes; development and implementation of QA/QI programs; experienced in personnel training and periodic competency testing, as well as meeting American Proficiency Institute standards for lab and personnel; and successfully passing a state audit without any citations or request for changes
 –Experience and formal education in clinical research management (pharmaceutical research)
 –More than 10 years of experience in laboratory testing— biological and analytical
 –Experienced program coordinator for genetic research project involving multiple universities

AMCO
JAN 11 2021



Form MJ-06: Marijuana Testing Facility Operating Plan Supplemental

4.2. Describe how the marijuana testing facility will ensure the scientific director and all testing analysts are proficient in utilizing testing equipment and analyzing samples:

We believe that all laboratories should demonstrate competency and adherence to internationally-accepted standards upon starting operations. Land & Seas Laboratory will immediately obtain accreditation to the International Organization for Standardization (ISO) 17025 standards for testing methods and quality assurance.

The Laboratory Director has developed policies and procedures to ensure:

- 1) Laboratory adherence to the ISO 17025 criteria and good lab practices (GLPs);
- 2) The laboratory will complete proficiency testing (PT) twice annually;
- 3) All personnel meet educational and experience requirements for the position;
- 4) All personnel are trained and complete competency testing with the Lab Director prior to being allowed to perform tasks independently and every six months afterward;
- 5) The laboratory will adhere to all state audit requirements detailed in the regulatory guidance document provided by DEC; and
- 6) The laboratory will follow the chain of custody regulations provided by AMCO for storage, management, and reporting of samples.

Section 5 – Testing Practices and Procedures

Review the requirements under 3 AAC 306.615, 3 AAC 306.635 – 3 AAC 306.650, and 3 AAC 306.660.

5.1. Describe each test the marijuana testing facility will offer:

See attached document. Form text box is not accepting more than one line of input.

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JAN 11 2021



Form MJ-06: Marijuana Testing Facility Operating Plan Supplemental

You must be able to certify each statement below. Read the following and then sign your initials in the corresponding box: Initials

5.2. I have attached the marijuana testing facility's written standard operating procedures manual that includes standard operating procedures for each test the facility will offer, as well as the acceptable range of results for each test.

JA

5.3. The written standard operating procedures manual is available to each employee at all times.

JA

5.4. Describe how the marijuana testing facility will meet the chain of custody requirements set forth in 3 AAC 306.650:

Samples must arrive at the laboratory in a lock box or tamper-proof container and accompanied by their unique METRC sticker(s) and a METRC manifest. If the METRC sticker(s) or manifest is missing, then the sample will not be accepted. Rejection of samples requires notification to the Lab Director or their designee immediately.

Required information will be recorded on the Sample Tracking & Results form and/or the L&S electronic Laboratory Information Management System to document sample condition, results, aliquot usage, and personnel handling samples. The unused portion of the sample will be kept in the locked sample storage closet inside the lab until all tests are completed, the results are reviewed, and the reports have been provided to customers. Processed sample material and unused leftover sample material will be disposed of in the manner detailed in the additional space section of this form and will be done under video surveillance and documented in METRC.

Land & Seas Laboratory will have ample surveillance in the form of video to be stored for 40 days at a secured location within the restricted access area on premises. All activities in the laboratory will be documented in this way and provided to AMCO upon request.

Section 6 – Reporting and Records Retention

Review the requirements under 3 AAC 306.670 and 3 AAC 306.675.

You must be able to certify the statement below. Read the following and then sign your initials in the box to the right: Initials

6.1. I have read, understand, and will comply with the timely reporting requirements set forth in 3 AAC 306.670(a).

JA

6.2. I have read, understand, and will comply with the reporting and validation requirements set forth in 3 AAC 306.670(b).

JA

6.3. I have read, understand, and will comply with the records retention requirements set forth in 3 AAC 306.675.

JA



Section 7 – Waste Disposal

Review the requirements under 3 AAC 306.740.

You must be able to certify the statement below. Read the following and then sign your initials in the box to the right: Initials

7.1. The marijuana testing facility shall give the board at least three days written notice required under 3 AAC 306.740(c) before making marijuana waste unusable and disposing of it.



7.2. Describe how you will store, manage, and dispose of any solid or liquid marijuana waste, in compliance with any applicable laws. Include details about the material(s) you will mix with ground marijuana waste and the processes that you will use to make the marijuana waste unusable for any purpose for which it was grown or produced:

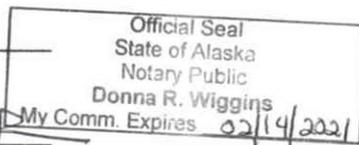
[Empty text box for description]

Form text box not accepting more than one line of text. See attachment for details.

I declare under penalty of unsworn falsification that this form, including all accompanying schedules and statements, is true, correct, and complete.

[Handwritten Signature]
Signature of licensee

JESSICA ALEXANDER
Printed name of licensee



Donna R. Wiggins
Notary Public in and for the State of Alaska

My commission expires: 02/14/2021

Subscribed and sworn to before me this 8th day of January, 2021.



Form MJ-06: Marijuana Testing Facility Operating Plan Supplemental

(Additional Space as Needed):

Hazardous waste will be generated by mixing organics solvents and cannabis in the course of sample preparation. Sample vials will be poured into a 5-gallon waste container in the lab, which will periodically be transferred to Rotavap to remove cannabinoids and purify solvents. The product of the Rotavap process will be added to the micro waste container and disposed of as described for that process below. The purified solvents will be transferred to a 30-gallon container in the video-monitored storage room. Once full, the 30-gallon container will be transferred to the Mat-Su Central Landfill for disposal in accordance with the Mat-Su Landfills guidelines with input from their site manager.

Once microbial testing has been completed, the used cannabis material in its growth media will be taken from the incubator and go directly into a 30-gallon sealable drum that contains bleach water. At the end of the day, the ground cannabis samples used for testing moisture content will be poured directly into the drum as well. Once all testing has been completed and the samples have been "cleared" in METRC, any leftover cannabis from those samples will be poured directly into the drum. Materials from cannabis by-product from the Rotavap solvent purification process will also be added to this bleach water/media mixture.

Periodically, cat litter will be added to the drum so that any cannabis, although already unusable due to being mixed in media and bleach water, will also be unrecognizable. Once the drum is full and a MJ-25 has been submitted to AMCO, it will be taken to the Mat-Su Landfill and the contents of the drum will be disposed according to the Mat-Su Landfills guidelines. Any cannabis that is not actively being used for testing or being prepared for destruction will be stored in a locked storage closet inside the locked lab.

AMCO

CHANGES TO MJ-06 SUPPLEMENTAL ARE AS FOLLOWS:

5.6.2 PCR Identification of STEC

LSL will test for and report the presence of STEC in any agricultural product by method of polymerase chain reaction using the Medicinal Genomics kit, which allows for the detection of the stx gene after microbial enrichment. Specific probes are used to detect DNA during the amplification by hybridizing to the amplicons. These probes are linked to fluorophores that fluoresce only when hybridized to the target sequences. In the absence of target DNA no fluorescence will be detected. As the amount of amplicon increases with each round of amplification, fluorescence intensity also increases. During each PCR cycle at the annealing step the detector measures this fluorescence and the associated software plots the fluorescence intensity versus the number of cycles. Presence of 1 or more CFU per gram constitutes failure of any sample. In addition to the Medicinal Genomics kits, Bio-Rad kits for PCR may also be stocked and their method of extraction for PCR may be used in the case of backorders or shortages in kits, reagents, or supplies. Both methods have been approved by DEC.

5.6.3 PCR Identification of Salmonella

LSL will test for and report the presence of Salmonella in any agricultural product by method of polymerase chain reaction using the Medicinal Genomics kit, which allows for the detection of the Salmonella gene after microbial enrichment. The technology is the same as detailed above. Presence of 1 or more CFU per gram constitutes failure of any sample. In addition to the Medicinal Genomics kits, Bio-Rad kits for PCR may also be stocked and their method of extraction for PCR may be used in the case of backorders or shortages in kits, reagents, or supplies. Both methods have been approved by DEC.

5.6.5 PCR Identification of Aspergillus

LSL will test for and report the presence of Aspergillus Niger, Flavus, and Fumigatus in any agricultural product by method of polymerase chain reaction using the Medicinal Genomics kit, which allows for the detection of the Salmonella gene after microbial enrichment. The technology is the same as detailed above. Presence of 1 or more CFU per gram constitutes failure of any sample. In addition to the Medicinal Genomics kits, Bio-Rad kits for PCR may also be stocked and their method of extraction for PCR may be used in the case of backorders or shortages in kits, reagents, or supplies. Both methods have been approved by DEC.



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JAN 11 2021

LICENSE# 10A-23634

VI SUPPLEMENT