Alcohol and Marijuana Control Office
550 W 7th Avenue, Suite 1600
Anchorage, AK 99501

Phone: 907.269.0350

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 the **Marijuana Establishment Operating Plan (Form MJ-01)**, 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 those 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 testing facilities?

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

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

This form must be submitted to AMCO's main office before any marijuana testing facility license application will be considered complete.

Section 1 – Establishment Information

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

Licensee:	The New Frontier Research LLC	**License Number:**	12657		
License Type:	**Marijuana Testing Facility**				
Doing Business As:	**The New Frontier Research**				
Premises Address:	**2301 South Knik-Goose Bay Road Unit #3**				
City:	**Wasilla**	**State:**	ALASKA	**ZIP:**	99654

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Section 2 – Prohibitions

Applicants should review 3 AAC 306.610 and be able to answer "Agree" to all items below.

The marijuana testing facility will not:	Agree	Disagree
Sell, deliver, distribute or transfer any marijuana or marijuana product to a consumer, with or without compensation	✓	☐
Allow any person to consume marijuana or marijuana product on its licenses premises	✓	☐

Section 3 – Testing Practices and Procedures

Review the requirements under 3 AAC 306.615, 3 AAC 306.635 – 3AAC 306.645, and 3 AAC 306.660, and identify how the proposed establishment will meet the listed requirements.

Describe each test the marijuana testing facility will offer:

The New Frontier Research will offer:

Potency Analysis for concentration of THC,THCA, CBD, CBDA and CBN.
- Marijuana plant material (flower and trim)
- Concentrates or extracts
- Products

Microbial screening for Shiga-toxin producing Escherichia Coli (STEC), Salmonella Species, Aspergillus fumigatus, Aspergillus Flavus, and Aspergillus niger.
- Marijuana plant material (flower and trim)
- Products

Residual Solvents:
- Concentrates or extracts

Foreign Matter Inspection:
- Marijuana plant material (flower and trim)
- Concentrates or extracts
- Products

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Standard Operating Procedure Manual (3 AAC 306.640):

Applicants for marijuana testing facilities must have a written procedures manual with detailed instructions explaining how to perform each testing method the applicant or marijuana testing facility uses, and minimum standards for each test. Applicants should be able to answer "Agree" to all items below.

The marijuana testing facility will ensure that the standard operating procedure manual:	Agree	Disagree
Is available to each employee at all times	☑	☐
Will cover at least the required procedures listed under 3 AAC 306.640	☑	☐

Describe the marijuana testing facility's standard operating procedure for each test the facility will offer:

Potency: Marijuana and marijuana concentrates and products will be tested for cannabinoid content and potency. Cannabis inflorescence (flowers) or "trim" will be used for potency testing. Plant material will be ground to make sure it is homogenous. The quartering method will be used to make sure the sample is homogenous and representative. Concentrate liquids will be thoroughly stirred or mixed before sampling to make sure samples are homogenous. Solids such, as resins, will be ground and thoroughly mixed before they are tested, and as with finished plant material, the quartering method will be used to obtain representative samples for testing. Samples will be tested per the attached protocols in a high performance liquid chromatograph with UV detector. Potency will be reported as the concentration in mg and as the % of product weight and must be within +/-10% standard deviation of the mean. The cannabinoid profile will be reported through METRC and to customers. The following cannabinoids will be profiled: d9-THC, d8-THC, THCA, THCV, CBD, CBDA, CBDV, CBG, CBGA, CBN, and CBC. THC and THCA will be combined for total concentration, as will CBD and CBDA. In edible product testing, the potency of each single serving in a multi-unit package will be reported and must be within 20 % of the manufacturer's target. Samples will be failed if the potency is more than 20% variation, the product is not homogenous from serving to serving in a multi-serving package, or there is more than 60 mg in the test lot package.

Microbial: Cannabis inflorescence (flowers) or "trim" will be used for potency testing. Plant material will be ground and the quartering method will be used to make sure the sample is homogenous and representative. Testing will be done by qPCR for detection of salmonella, STEC (shiga-toxin producing escherichia coli) and Aspergillus fumigatus, Aspergillus flavus and Aspergillus niger per the attached protocols.

Residual Solvents: Using an analytical balance, 100 mg of sample concentrates or extracts will be measured out and placed in testing vial to be evaluated for the presence of Butanes, Heptanes, Benzene, Toluene, Hexane and total Xylenes (meta-xylenes, para-xylenes, or ortho-xylenes) using a head space gas chromatography with mass spectrometry per attached protocols.

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Laboratory Testing of Marijuana and Marijuana Products (3 AAC 306.645):

A licensed marijuana testing facility must meet minimum standards for laboratory testing. Applicants should be able to answer "Agree" to all items below.

The marijuana testing facility applicant has:	Agree	Disagree
Read and understands and agrees to the requirements listed under 3 AAC 306.645	☑	☐

Describe the acceptable range of results for each test the marijuana testing facility will offer:

Potency:
All test results will undergo a technical review in order to ensure product meets acceptable standards. Potency will be reported as the concentration in mg and as the % of product weight and must be within +/-10% standard deviation of the mean.

Microbial Screening:
- Less than 1 (one) colony forming unit (CFU/g) is the acceptable limit for Shiga-toxin producing Escherichia Coli (STEC), Salmonella species and Aspergillus fumigatus, Aspergillus flavus, and Aspergillus niger-fungus. If greater than or equal to 1 (one) colony-forming unit is detected in a one-gram sample then the sample is failed.

Solvents:
- Solvent-based concentrates are tested for residual solvent content. Results are in parts per million (ppm).

Acceptable Limits per Gram are:
-Butanes: less than 800 parts per million (ppm)
-Heptanes: Less than 500 parts per million (ppm)
-Benzene: Less than 1 parts per million (ppm)
-Toluene: Less than 1 parts per million (ppm)
-Hexane: Less than 10 parts per million (ppm)
-Total Xylenes (meta-xylenes, para-xylenes, or ortho-xylenes): Less than 1 parts per million (ppm) ***If a sample exceeds any one of these concentration levels, the sample is failed.

Foreign Matter: FDA Standards based on The Defect Levels Handbook
-Samples will be inspected for human hair, insect parts, non-mammalian hairs or feathers and the sample will be failed for presence of more than 1 per gram.
-Samples will be inspected for miscellaneous matter (soil, sand, etc) and the sample will be failed for the presence of more than 5 fragments per gram.

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Section 4 – Employee Qualification and Training

Review the requirements under 3 AAC 306.625 – 3 AAC 306.630, and identify how the proposed establishment will meet the listed requirements.

Proficiency Testing Program (3 AAC 306.625):

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

It is our belief that cannabis laboratories should be mandated to demonstrate competency through an internationally-accepted standards that has been developed for proper analytical laboratory operations. The New Frontier Research will demonstrate competency by immediately pursuing accreditation by the International Organization for Standardization (ISO) 17025 standards within 12 months. ISO standards cover testing and calibration performed using standard methods, non-standard methods, and laboratory developed methods. ISO standards are not ambiguous and are universally accepted. To achieve accreditation, this testing facility will work with a third-party ISO 17011-accredited ILAC to provide assurance that the laboratory produces consistent and reliable results according to ISO 17025 criteria for cannabinoid potency measurement (THC and CBD). The third-party organizations which conduct the Inter-laboratory Proficiency Tests (IPT) must also be certified by ISO, under yet another set of standard criteria, ISO 17043.

The Laboratory Director will develop policies and procedures to ensure that:
the laboratory follows the ISO 17025 criteria, including good lab practices (GLPs);
maintains internal standard operating procedures and quality controls;
instruments are properly calibrated, maintained, and repaired; and
that the lab follows an adequate chain of custody protocol to store and manage samples.

Initial training on equipment and methods-- The New Frontier Research has contracted with a Shimadzu training team to have their PhD and equipment representative come to our site for 3 days of on-site training in methodology and equipment trouble-shooting. All laboratory technicians will be required to attend this initial training in its entirety. Thereafter, regular proficiency testing will be done every 6 months to ensure the reliability of the laboratory's methods and to help monitor performance for specific tests or measurements. Proficiency testing requires that the laboratory analyzes one or more samples of unknown composition provided by an independent third party. The laboratory measures the samples according to a given set of instructions and reports the results to the administrator of the test. The values reported by the laboratory are compared to an average, or study mean, and the reference (assigned) value. The results are considered "acceptable" if they fall within the acceptance limits

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Scientific Director (3 AAC 306.630):

All marijuana testing facilities must employ a scientific director with responsibilities and qualifications set out in 3 AAC 306.630 and 3 AAC 306.640(b).

Name the scientific director and describe how he/she meets the qualifications set out in 3 AAC 306.630(b).

Jessica Alexander, 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. Participated in graduate school research analyzing frozen procine 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 in the state of Alaska for 2 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

Section 5 – Security

Review the requirements under 3 AAC 306.650, and identify how the proposed establishment will meet the listed requirements.

Chain of Custody (3 AAC 306.650):

Describe how the marijuana testing facility will meet the chain of custody requirements as listed in this section:

Samples must arrive at TNFR in an approved container with a tamper-proof seal and must be marked with a unique METRC identifier and accompanied by a METRC manifest. If the sealed METRC identifier or manifest is missing, then the sample will not be accepted. Before any analysis is started, the required information will be recorded on the Sample Receiving & Tracking form, entered into the METRC system and to the TNFR Laboratory Information Management System, and the sample will be placed in secure area. The storage and movement of product samples within the TNFR premises will be tracked on the lower portion of the Sample Receiving & Internal tracking form (see attached). Samples removed for testing will be noted on this form. The unused portion of the sample will be kept in the secure storage area until all requested tests are completed and the results are reviewed. Marijuana waste and unused samples will be rendered unusable by mixing them with used organic solvents and disposed of in the organic waste barrels, in view of video surveillance system.

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Section 6 – Reporting and Records Retention

Applicants should review 3 AAC 306.670 – 3 AAC 306.675 and be able to answer "Agree" to all items below.

Reporting, Verification (3 AAC 306.670):

The marijuana testing facility applicant:	Agree	Disagree
Has read, understands, and agrees to the reporting requirements outlined in 3 AAC 306.670(a)	☑	☐
Has read, understands, and agrees to the reporting requirements outlined in 3 AAC 306.670(b)	☑	☐

Records Retention (3 AAC 306.675):

The marijuana testing facility applicant:	Agree	Disagree
Has read, understands, and agrees to the records retention requirements listed in 3 AAC 306.675	☑	☐

I declare under penalty of perjury that I have examined this form, including all accompanying schedules and statements, and to the best of my knowledge and belief find it to be true, correct, and complete.

Signature of licensee

Jessica Alexander

Printed name

Subscribed and sworn to before me this 19 day of April, 2017.

Official Seal
Robert H. Smith
Notary Public-State of Alaska
My Comm. Expires 11/09/2020

Notary Public in and for the State of Alaska.

My commission expires: 11/09/2020

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(Additional Space as Needed):

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