



# Department of Health

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Executive Deputy Commissioner

**Date: May 3, 2019**

**Purpose of Solicitation:** This letter is for informational purposes, to communicate the opportunity for commercial laboratories to perform testing of medical marijuana products in NYS.

**Description of Testing Opportunities:** The testing is of each lot of fully produced and packaged medical marijuana products manufactured by the ten Registered Organizations approved by the New York State Department of Health (NYSDOH). Product forms to be tested include, but are not limited to: capsules; tablets; lozenges; oral sprays, oils, powders or tinctures; soft-gel chews; topical lotions; suppositories; vaporization cartridges; metered ground flower for vaporization; and multi-dose inhalers.

Testing will be performed on the following analytes:

- Cannabinoid potency (initial)
  - o Tetrahydrocannabinol (THC)
  - o Tetrahydrocannabinol acid (THCA)
  - o Tetrahydrocannabivarin (THCV)
  - o Cannabidiol (CBD)
  - o Cannabinadiolic acid (CBDA)
  - o Cannabidivarin (CBDV)
  - o Cannabinol (CBN)
  - o Cannabigerol (CBG)
  - o Cannabichromene (CBC)
  - o Any other cannabinoid component at > 0.1%
- Total THC and CBD stability (based on potency)
  - o Testing opened products at 60 days or as determined by NYSDOH
  - o Testing unopened products at 6 and 12 months or as determined by NYSDOH
- Contaminant testing
  - o Heavy metals
    - Antimony
    - Arsenic
    - Cadmium
    - Chromium
    - Copper
    - Lead
    - Nickel
    - Zinc
    - Mercury
  - o Growth regulators and pesticides
    - as declared by the Registered Organizations
  - o Microbiology
    - E. coli
    - Pseudomonas (for products to be vaporized)

- Salmonella species
- Enterococcus species
- Bile tolerant gram-negative bacteria, specifically including Klebsiella species
- Aspergillus species
- Mucor species
- Penicillium species
- Thermophilic Actinomycetes species
- o Mycotoxins
  - Aflatoxins B1, B2, G1, G2
  - Ochratoxin A
- o Any other analyte as required by the NYSDOH Commissioner

Further information on analytes and NYSDOH-approved methods are available at: [http://www.wadsworth.org/sites/default/files/WebDoc/1706557002/180\\_MM\\_methods.pdf](http://www.wadsworth.org/sites/default/files/WebDoc/1706557002/180_MM_methods.pdf). Visit the medical marijuana program webpage for updates on the status of any regulatory changes [https://www.health.ny.gov/regulations/medical\\_marijuana/regulations.htm](https://www.health.ny.gov/regulations/medical_marijuana/regulations.htm).

**Eligible Organizations:** Laboratories seeking accreditation must be located in NYS and will be required to provide evidence of the proper controlled substance license from the NYSDOH Bureau of Narcotic Enforcement (BNE). Laboratories interested in obtaining a controlled substance license may call the toll free BNE call center line at (866) 811-7957 and follow the prompts for information on a license to engage in controlled substance activity. Instructions and the License Application to Engage in a Controlled Substance Activity in NYS can be found at [http://www.health.ny.gov/professionals/narcotic/licensing\\_and\\_certification/licensing.htm](http://www.health.ny.gov/professionals/narcotic/licensing_and_certification/licensing.htm). Laboratories with the appropriate BNE approval in place can apply for the required NYSDOH Environmental Laboratory Approval Program (ELAP) approval for testing, see: <http://www.wadsworth.org/regulatory/elap/medical-marijuana> .

**Approval Process:** The laboratory will:

- a. Apply using the ELAP Medical Marijuana application form, and submit all relevant Standard Operating Procedures, validation data as requested, and documentation of staff demonstration of capabilities
  - b. Successfully complete an on-site assessment by ELAP staff
- Participation in a proficiency test may be required in the future
  - Accreditation is by ELAP (New York State) only. The NYSDOH will not recognize any other state's or organization's accreditation for such testing.

**Other opportunities:**

There are also opportunities for in-process testing of bulk extracts to be sold wholesale or to support research and development of new products.

Additionally, new testing opportunities exist in the Industrial Hemp Program, currently administered by the NYS Department of Agriculture & Markets. Testing of the plants to verify a THC content of < 0.3% is required, and there will be opportunities for potency and contamination testing of hemp products meant for human consumption. The NYS program has expanded significantly with the signing of the 2018 Farm Bill.

In the future, there may be testing opportunities associated with adult use cannabis in NYS. Progress on this legislation should be monitored for new testing opportunities.

**Due Date:** Applications for approval by ELAP to perform testing on medical marijuana products in NYS will be accepted on an ongoing basis.

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Environmental Laboratory Approval Program (ELAP)

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