



SOLICITATION OF INTEREST (SOI) FOR LABORATORIES TO PERFORM TESTING OF MEDICAL MARIJUANA PRODUCTS IN NEW YORK STATE

Date: November 29, 2016

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

Description of Testing Opportunities: The testing is of medical marijuana products produced by Registered Organizations registered with the New York State Department of Health (NYSDOH). Products to be tested include, but are not limited to: capsules, oils or tinctures and vaporization cartridges. Testing will be performed on the following analytes:

- Cannabinoid potency
 - Tetrahydrocannabinol (THC)
 - Tetrahydrocannabinol acid (THCA)
 - Tetrahydrocannabivarin (THCV)
 - Cannabidiol (CBD)
 - Cannabinadiolic acid (CBDA)
 - Cannabidivarin (CBDV)
 - Cannabinol (CBN)
 - Cannabigerol (CBG)
 - Cannabichromene (CBC)
 - Any other cannabinoid component at > 0.1%
- Total THC and CBD stability (based on potency)
 - Testing opened products at 30 and 60 days or as determined by NYSDOH
 - Testing unopened products at 4, 8 and 12 months or as determined by NYSDOH
- Contaminant testing
 - Heavy metals
 - Antimony
 - Arsenic
 - Cadmium
 - Chromium
 - Copper
 - Lead
 - Nickel
 - Zinc
 - Mercury
 - Growth regulators and pesticides
 - As declared by registered organizations
 - Microbiology
 - E. coli

- Klebsiella
- Pseudomonas (for products to be vaporized)
- Salmonella
- Streptococcus
- Bile tolerant gram negative bacteria
- Aspergillus
- Mucor species
- Penicillium species
- Thermophilic Actinomycetes species
- o Mycotoxins
 - Aflatoxin
 - Ochratoxin
- o Any other analyte as required by the NYSDOH Commissioner

Further information on analytes and NYS DOH Wadsworth Center-approved methods are available at:

http://www.wadsworth.org/sites/default/files/WebDoc/1706557002/180_MM_methods.pdf.

Please note additional forms and changes in the analytes to be tested are under consideration. Visit the medical marijuana program webpage for updates on the status of any regulatory changes http://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) and registration with the U.S. Department of Justice Drug Enforcement Administration (DEA). 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. The application for DEA registration can be found at <https://www.deadiversion.usdoj.gov/webforms/>. Laboratories with the appropriate DEA and BNE approvals 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 twice a year 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.

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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