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Environmental Laboratory Approval Program (ELAP) and Laboratory of Environmental Biology (LEB)

Guidance Document for the Use of PathogenDx Detect-NY Microarray for Analysis of NYS Medical Marijuana Products

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The validated assay or method has limitations. It is unable to do the following:

1. detect bile tolerant gram negative (BTGN) bacteria,
2. detect *Pseudomonas* spp.,
3. enumerate aerobic bacteria, and
4. enumerate molds.

Laboratories will have the following options to use along with the validated assay.

Testing Option #1 – Detection in Diluted Sample Aliquots

1. Method
    a. The microarray instructions indicate to dilute 1g of product 1:10 and use one tenth of diluted product for analysis. Dose sizes of medical marijuana products vary greatly, and laboratory SOPs will need to document procedures for analyzing samples with dose sizes above and below 1g or 1mL.
    b. As per NYSDOH LEB-603, a total of 20 doses are pooled from the containers received from the Registered Organization.
    c. As per NYSDOH LEB-603, 15 or more of the pooled doses are combined and diluted at least 1:10 with PBST (each diluted dose is now called a diluted aliquot).
    d. Remove one tenth of the total volume of the combined diluted doses and proceed with microarray sample analysis.
    e. Remove one tenth of the total volume of the combined diluted doses and proceed with microarray matrix spike sample analysis (if needed).
    f. As per NYSDOH LEB-604, from the combined diluted doses, remove one diluted aliquot for each of the following analyses and proceed with Section 9.3:
        i. Bile tolerant gram-negative bacteria
        ii. Bile tolerant gram-negative bacteria matrix spike (if needed)
    g. As per NYSDOH LEB-604, from the combined diluted doses, remove one diluted aliquot for each of the following analyses and proceed with Section 9.2:
        i. *Pseudomonas* spp.
        ii. *Pseudomonas* spp. matrix spike (if needed)
    h. As per NYSDOH LEB-605, from the combined diluted doses, remove one diluted aliquot for each of the following analyses:
        i. Aerobic plate count
        ii. Aerobic plate count matrix spike
2. Matrix spikes
    a. Laboratories using the microarray for detection in diluted sample aliquots will not be able to apply their past matrix spike results. You will need to perform matrix spikes for each sample type as described in NYS DOH LEB-603 section 9.2. as if they had not been analyzed before.
3. Demonstration of capability
    a. Guidance for initial and ongoing demonstrations of capability is available on the ELAP website.

Testing Option #2 – Identification of Isolated Contaminants

1. Method
    a. Follow NYS DOH LEB-603, 604, and 605 as written.
    b. Use the microarray to identify organisms found in the samples in lieu of the selective agar Methods (i.e., NYS DOH LEB-607, 608, 609, 611, 612, 613, and 618).
    c. NYS DOH LEB-606 and 610 are still used to identify BTGN and *Pseudomonas* spp.
2. Matrix spikes
    a. Laboratories using the microarray for identification of isolates do not need to adjust their tally of matrix spikes.
3. Demonstration of capability
    b. Guidance for initial and ongoing demonstrations of capability is available on the ELAP website.