GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

August 10, 2020

To Whom It May Concern:

The MRA has received several complaints regarding the use of quantitative polymerase chain reaction (qPCR) test methods for the required quantitation of Total Yeast & Mold and Total Coliforms. After thorough review of the qPCR method validations, it has come to our attention that several critical pieces are missing or were not done to the current standard AOAC appendix J.

- The validation cited referenced a peer-reviewed study that guided validation for qualitative detection of organisms using a PCR method.
- The validation criteria for the qPCR method was based on guidelines for qualitative analysis and not quantitative.
- The organism species chosen are not typical contaminates you would find on plants nor in manufacturing including *Klebsiella pneumoniae* and *Saccharomyces cerevisiae.*
- The validation was not conducted on naturally contaminated product matrix nor did it use naturally contaminated matrix as a source of inoculum.
- Reasonable variations of the method were not assessed, variations in method parameters that can be influenced by the end user should be tested. The method developer is expected to make a good faith effort to choose parameters that are most likely to affect the analytical performance and determine the range of variations that can occur without adversely affecting analytical results. Five replicates at each target concentration and five replicates of the nontarget are tested for each factorial pattern.
- The reconstitution and inoculation of *Aspergillus* species did not follow the manufacture instructions.

The MRA has published requirements for methods and validations. Licensees cannot use a method without first demonstrating that the method produces scientifically accurate and reliable results.

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
LANSING

ORLENE HAWKS
DIRECTOR

Rule 5(2) in the Marihuana Sampling and Testing rule set R. 420.305(2) states:

A laboratory shall use analytical testing methodologies for the required safety tests in subrule (3) of this rule that are validated by an independent third party and may be monitored on an ongoing basis by the agency or a third party. In the absence of reference to compendia or published methods, Appendix K of Official Methods of Analysis authored by the Association of Official Analytical Chemists must be published in full. The agency shall approve the validated methodology used by the laboratory and confirm that it produces scientifically accurate results for each safety test it conducts.

All licensees who are currently using a qPCR method for Total Yeast & Mold and Total Coliforms have 3 options:

1. The lab may switch to a method validated by an independent third party.
2. The lab may opt to follow the entirety of Appendix J and validate the methodology themselves.
3. The lab may opt to pair qPCR with plating as confirmation. The plating method chosen must be validated by an independent third party and verified in the laboratory.

Laboratories receiving this letter are required to submit updated validation documents to the MRA no later than September 10th, 2020. If you have any questions, please reach out to MRA-SCF@michigan.gov for assistance.

Sincerely,

MRA Scientific & Legal Section